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IN THE

Supreme Court of the United States

OCTOBER TERM, 1959.

No. 366

CARTER PRODUCTS, INC.,

Petitioner,

v.

FEDERAL TRADE COMMISSION,

Respondent.

PETITION FOR A WRIT OF CERTIORARI.

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v.

FEDERAL TRADE COMMISSION,

Respondent.

PETITION FOR A WRIT OF CERTIORARI.

The Petitioner, Carter Products, Inc. prays that a writ of certiorari issue to review the judgment and decree of the Court of Appeals for the Ninth Circuit, filed and entered on July 28, 1959, affirming and enforcing the Federal Trade Commission's Cease and Desist Order dated October 4, 1956.

Opinions Below.

The Opinion of the Court of Appeals, filed June 16, 1959, and not yet officially reported, the Opinion of the Federal Trade Commission, filed October 4, 1956, and the Opinion of the Court of Appeals on the former appeal in this case, reported in 201 F. (2) 446 and of this Court, reported in 346 U. S. 327, because of their length, are contained in a separate Appendix filed herewith.

The Commission found that Carter's therapeutic claim that its product, Carter's Little Liver Pills, increases bile flow was not substantiated and permanently enjoined the advertising of that claim and the dissemination of any advertisement in which the word "Liver" is used in the trade name of the product. The Court of Appeals affirmed the Order and directed its enforcement. It is to this claim alone and to these provisions of the Order only as affirmed by the Court of Appeals that the present application is directed.

The finding in question is:

> "The greater weight of the testimony and other evidence introduced into the record supports informed determinations that the preparation Carter's Little Liver Pills will not stimulate the formation of bile by the liver or increase the secretion of bile by the liver" (Vol. V, 303).*

The provisions of the Order in question are the provisions which prohibit the making of an advertisement representing:

> "(e) That said preparation is an effective treatment for sluggish liver function or that it will have any therapeutic action on any condition, disease or disorder of the liver,"
>
> "(f) That said preparation will make bile flow freely, increase or beneficially influence the formation, secretion or flow of bile, * * *."
>
> "(g) * * * that it possesses therapeutic properties in addition to those afforded by laxative action." (Vol. V, 312)

*The references are to the consolidated record in this case filed with this Petition as certified by the Clerk of the Court of Appeals in Case No. 12,940 and Case No. 15,373 and renumbered consecutively as Vols. I through XV and to the Exhibits contained in Parts 12 through 21.

, and which prohibit Petitioner from

> "(2) Disseminating • • • any advertisement • • • in which the word 'Liver' is used in the trade name for the respondent's preparation" (Vol. V, 313).

Jurisdiction.

The judgment and decree of the Court of Appeals was entered on July 28, 1959 and is appended as Appendix A. The jurisdiction of this Court is invoked under 28 U. S. C. 1254 (1) and 15 U. S. C. 45.

Questions Presented.

The Federal Trade Commission, enjoined the advertising of Petitioner's claim that the ingredients of its product, Carter's Little Liver Pills, increase bile flow, as well as the dissemination of any advertising in which the word "liver" is used in the trade name of the product. The ingredients of Carter's Little Liver Pills are the vegetable drugs, of the same plant kingdom as American penicillum, known as aloes and podophyllum. The medical issue in the case, therefore, was whether these drugs in fact aid bile flow—that is, whether they have a direct action on the liver which increases bile flow, or additionally or in the alternative, whether such drugs relieve constipation and, by so doing, increase bile flow. The Commission did not prove or find that the falsity of the therapeutic claim had been established by general informed medical opinion or by test procedures thereby approved. The Court of Appeals (viewing the evidence in the light most favorable to the Commission's findings) recognized (Opinion, Appendix pp. 51-52) that no general consensus of informed medical opinion supported the Commission's determination

that these drugs do not aid in increasing bile flow, and that medical experts have reached different conclusions on this subject; the Court disavowed any ability on its part to resolve the conflict. It nevertheless permitted the Commission to do so, and supported the Commission's decision by applying the customary substantial evidence rule. On this background, the following questions are presented:

(1) In the circumstances of this case, involving the alleged falsity of therapeutic claims concerning a medical preparation consisting of specified drugs, was the Court of Appeals correct in permitting the Federal Trade Commission to pick and choose among conflicting medical opinions concerning the truth of the claim and in testing the validity of the Commission's findings by the customary rule of substantial evidence, or did the applicable law, and in particular the Wheeler-Lea amendments to the Federal Trade Commission Act, require the Court and Commission to employ a higher standard of certainty, in particular that of general medical agreement or consensus of informed medical opinion?

(2) Was the Court of Appeals' failure to pass specifically upon Petitioner's specific contentions that the proceedings before the Commission lacked that essential fairness required both by the statute and procedural due process under the Fifth Amendment, a proper discharge of the duties imposed on the Court of Appeals as a reviewing Court by this Court's decisions in *Automatic Canteen Co.* v. *Federal Trade Commission*, 346 U. S. 61, and *Universal Camera Corp.* v. *N. L. R. B.*, 340 U. S. 474?

Statute Involved.

The statute involved is the Federal Trade Commission Act as amended by the Wheeler Lea Amendments adopted in 1938, 15 U. S. C., Sections 45 and 52-58, the pertinent provisions of which, because of their length, are set forth in Appendix B attached to this Brief.

Statement.

This proceeding was begun by complaint of the Federal Trade Commission filed May 28, 1943 charging Carter with alleged false advertising of its product, Carter's Little Liver Pills, a nationally known proprietary drug sold for over 70 years throughout the United States (Vol. I, 22). The charges in the complaint were denied in Carter's answer filed July 9, 1943 (Vol. I, 29).

On a prior appeal to the Court below the Commission's Order was set aside on the ground that the cumulative effect of the Hearing Examiner's rulings, exclusions of evidence and unwarranted restrictions on Carter's right of cross examination of the Commission's principal expert witnesses had deprived Carter of due process and of its right to a fair trial (201 F. 2d 446). On certiorari this Court (346 U. S. 327) vacated the judgment of the Court of Appeals and amended it by remanding the case for further hearings in accordance with the Court of Appeals' previous opinion.

Carter's second appeal to that Court, which has resulted in its present decree, presented the *same* contention (*now presented to this Court*) that under the Wheeler-Lea amendments to the Federal Trade Commission Act the Commission was not free to pick and choose among the conflicting opinions of experts in dealing with an issue relating to the advertising of medical products, and that, where

there was no general consensus of informed medical opinion which challenged the therapeutic claims in issue, and a substantial difference in medical opinion was shown, the Commission could not issue a cease and desist order. Carter also contended that by the same type of prejudicial errors Carter had, as regards this specific therapeutic claim, once again been deprived of its right to a fair trial. The specific charges of denials of due process upon which Carter relied on its second appeal were presented to that Court which affirmed the Commission's Order *without passing specifically on those contentions.*

The sole disposition which the lower Court made of Carter's contentions concerning the effect of the Wheeler Lea Amendments to the Act, *the major legal issue in this case;* was to state in passing, *without giving its reasons,* that "*Parenthetically,* we point out that we *disagree* with Carter's contention concerning the effect of these amendments" (Opinion, Appendix p. 51). The Court believed, as pointed out above, that it was compelled to permit the Commission to resolve conflicts in the testimony of medical experts even where there existed a substantial difference of medical opinion as to the truth or falsity of a therapeutic claim.

No other advertising claim of Carter and no exaggeration, if any, in the advertising of this therapeutic claim is involved. So far as the Commission's Order enjoins any exaggerated advertising statement of this therapeutic claim or any other advertising claim no review or modification of the Commission's Order is sought. The sole relief requested is the elimination from the Commission's Order of the provisions above set forth and the setting aside of the lower Court's decree insofar as it affirms those provisions.

Reasons for Granting the Writ.

The present case plainly satisfies the criteria for certiorari established by this Court's Rule 19. These grounds are summarized at this point and developed further under headings corresponding to the lettered designations which follow:

(A) As originally enacted, Section 5 of the Federal Trade Commission Act banned "unfair methods of competition in commerce." The Wheeler-Lea amendments, of 1938, 38 Stat. 111, added to this prohibition "unfair or deceptive acts or practices in commgree." The 1938 amendments, in addition, added several new sections to the Act, dealing specifically among other matters with the false advertising of drugs. 38 Stat. 111, as codified at 15 U. S. C. 52 *et seq.* The Committee Reports on the Wheeler-Lea amendments, as shown below, specifically acknowledged that Congress may not, on grounds of policy and constitutional power, by an unqualified prohibition against misleading representation, penalize a therapeutic claim concerning the truth of which qualified opinion differs, and referred, among other authorities, to the decision of this court in *American School of Magnetic Healing* v. *McAnnulty*, 187 U. S. 94. The effect of the Wheeler-Lea amendments as applied to the standard of proof required in determining the truth or falsity of therapeutic claims manifestly presents an important question of federal law which has not been, but should be, settled by this Court.

In declining to give any effect to the strict standard of proof required by the Wheeler-Lea amendments as applied to therapeutic claims, namely proof of falsity of the claim by general medical agreement or consensus of informed medical opinion, the Court below has rendered a decision which conflicts in prin-

ciple with applicable decisions of this Court. Such decisions as *Universal Camera Corp.* v. *Labor Bd.*, 340 U. S. 474, establish that the standard of proof to be applied by the Courts of Appeal in reviewing agency action must be in exact compliance with that prescribed by Congress in the particular circumstances. What is here involved, essentially, is the right of a business, in connection with its manufacture and sale of a harmless medical product, to proclaim to the public its opinion, honestly held and supported by a respectable body of medical authority, that the product has specified therapeutic qualities. To empower an administrative agency to deny such a right in these circumstances where a substantial conflict in the status of medical opinion is shown raises critical questions under the First and Fifth Amendments to the Federal Constitution. The lower Court's decision conflicts in principle with the decisions of this Court in the *McAnnally* case, *supra*, and *Reilly* v. *Pinkus*, 338 U. S. 269.

The decision below conflicts specifically in principle and result with the desisions of other courts of appeal interpreting the Act as amended by the Wheeler-Lea amendments in *Belmont Laboratories* v. *Federal Trade Commission*, 103 F. 2d 538 (3d Cir.) and *Alberty* v. *Federal Trade Commission*, 182 F. 2d 36, 40-41 (D. C. Cir.), certiorari denied, 340 U. S. 818 and with other Circuit Court decisions hereafter referred to.

In summarily disposing of the Wheeler-Lea amendments, the Court below failed to note that the Federal Trade Commission itself had initially recognized the strict standard of proof which they require in dealing with therapeutic claims. *Federal Trade Commission* v. *Lambert Pharmacal Co.*, Docket No. 4232; dismissed May 3, 1944. By a gradual process of neglect, over the intervening years, the Commission apparently has now come to disregard these amendments in cases such as this.

The Wheeler-Lea amendments may not be disregarded in so far as they erect a different standard of proof applicable to product therapeutic claims. The effort of the Commission to nullify them, as countenanced by the Court below, calls for an exercise of this Court's power of supervision.

(B) A brief reference to the record in the case demonstrates the fact that there is no general consensus of qualified medical opinion which supports the Commission's determination that Carter's Little Liver Pills do not aid the flow of bile; on the contrary, even viewing the evidence most favorably to the Commission's decision, a respectable body of medical opinion holds that the product does have this salutary effect. The Commission's decision shows that it simply picked and chose the testimony which it preferred. It did not even make a finding that the falsity of the claim had been established by proof of nonsensus of medical opinion or any finding of the absence of a conflicting body of medical opinion. Its opinion (Vol. V, 3140), on the contrary, expressly concedes the existence of "conflicts in the evidence," and the Opinion of the Court below indicates clearly the existence in this case of a substantial difference in the status of medical opinion. (Opinion, Appendix pp. 51-52).

(C) The lower Court's failure to pass specifically on the Petitioner's specific contentions as to the essential unfairness and duality of the methods and standards of proof used by the Commission and the defects in its proof was reversible error and is in conflict with the requirements of the decisions of this Court in *Gratz et al. Claiborne Co. v. Federal Trade Commission*, 316 U. S. 61 and *Universal Camera Corp. v. N. L. R. B.*, 340 U. S. 474.

A.

The Legislative History of the Wheeler Lea Amendments to the Federal Trade Commission Act Demonstrates that the Existence of a Substantial Conflict in the Status of Qualified Medical Opinion Is a Defense to the Commission's Assertion of the Falsity of a Product Therapeutic Claim and to its Suppression of that Claim by Cease and Desist Order.

No proof was adduced and no finding was made by the Commission that the therapeutic claim in question was not a harmless, honest therapeutic claim and no evidence of questioning or contradiction of the claim prior to the institution of this proceeding or of customer complaints or injury through the use of the drug was produced though the product has been nationally sold and used for some three quarters of a century. Both the former and present Orders of the Commission recognize the harmlessness of the product and its effectiveness as a laxative.

The legislative history of the Wheeler-Lea Amendments to the Federal Trade Commission Act squarely establishes the following proposition:

Constitutional requisites of certainty in the Act and important considerations of policy, explicitly acknowledged by the Congress, forbade it to place product therapeutic claims at the mercy of the individual opinions of any one group of medical experts where, as here, the subject concerns a medical controversy on which qualified medical opinion is in substantial disagreement. Accordingly the Act prescribes a special standard of certainty of proof with regard to an administrative determination of the falsity of a therapeatic claim. The standard selected was general medical agreement or consensus of qualified medical opinion. That standard was not complied with in the present case.

The Commission correctly recognized this legislative standard in its landmark decision in *Federal Trade Commission* v. *Lambert Pharmacal Co., supra*, decided a few years after the Wheeler Lea Amendments, in which "differences of opinion among experts as to the acceptability of various test procedures" formed one of the bases for its dismissal of the complaint. (Concurring Opinion of Commissioner March.)

The issue is one of vital significance. Censorship and suppression applied today to the therapeutic claims of a proprietary medicine, where a substantial conflict in qualified medical opinion concerning their truth or falsity is found to exist, may be applied tomorrow, for example, to the Salk serum or to the "wonder drugs". There is no intention in the Act that the Commission should "become the absolute arbiter of the truth * * *, even where scholars in the particular field of knowledge were in wide disagreement". *Scientific Mfg. Co.* v. *Federal Trade Commission*, 124 F. 2d 640, 644 (3rd Cir.). In such case "a non-expert Board can hardly have been intended to be umpire". *Raladam Co.* v. *Federal Trade Commission*, 42 F. (2) 430, 434-5 (6th Cir.) aff'd on other grounds, 283 U. S. 643.

There is no express mention in the Federal Trade Commission Act of therapeutic claims. There is only the general provision of Title 15 U. S. C. Section 55(a) (Appendix B, P. 9a) to the effect that an advertisement is a violation of the statute if it is false or misleading in a material respect either because of an express representation or because of an omission to state facts material in the light of such representation. In *U. S.* v. *Johnson*, 221 U. S. 488, this Court held that a statute in this form did not apply to therapeutic claims. Recourse therefore to legislative history is essential to determine the extent to which such claims are subject to the present Act and the stand-

ard of proof requisite to establish the falsity of such claims. *Federal Trade Commission* v. *Raladam Co.*, 283 U. S. 643, 649-652; *F. T. C.* v. *Bunte*, 312 U. S. 349, 352; *U. S.* v. *Dotterweich*, 320 U. S. 277, 281-2.

The legislative history of the Wheeler-Lea Amendments to the Federal Trade Commisison Act and its companion legislation the Food and Drug Act made in 1938, so far as it relates to therapeutic claims, over-lapped. It is to the identically serious problems of policy and constitutional power with regard to the suppression of therapeutic claims which both acts posed that the discussions in both sets of legislative reports are addressed.

House Report No. 1613 (75th Congress) on the Wheeler Lea Amendments states "A problem of some difficulty exists in the case of advertisements where there are differences of opinion. Perhaps the problem is most acute in the case of claims regarding the curative effect of drugs. The difficulty has two aspects—one of policy and the other of congressional power."

"As to the legal problem," the House Report states, "it is a well known principle of law that a statute providing punishment for the commission of an offense must describe the offense with a reasonable degree of certainty. There are clear implications in cases arising under the Food and Drug Act of June 30, 1906, that Congress may not penalize the making of a statement regarding the truth of which qualified opinion differs (*Seven Cases* v. *United States*, 239 U. S. 510; *United States* v. *Johnson*, 221 U. S. 488. See also *American School of Magnetic Healing* v. *McAnnulty* (187 U. S. 94))." The Comment in House Report No. 2139 (75th Congress) on the Food and Drug Act is identical except that the sentence which cites these same authorities ends with the phrase "Congress may not, by a simple and unqualified prohibition against misleading representation,

penalize the making of a representation of therapeutic effect regarding the truth of which expert opinion differs."

House Report No. 1613 on the Wheeler Lea Amendments states that "the reason for this limitation on the power of Congress is apparent," namely that "if Congress were to provide that a representation, as to the correctness of which qualified opinion differed, would be misleading if the jury agreed with the experts holding one view, but not misleading if the jury agreed with the experts holding the other view", * * * "there would therefore exist the kind of uncertainty which would invalidate the statute." The comment in House Report No. 2139 on the Food and Drug Act is identical.

The legislature was omitting from the Act all requirement of proof of fraud which had been the stumbling block in the enforcement of prior legislation and substituting therefor a method of suppression by permanent injunction of harmless therapeutic claims honestly made. It, therefore, acknowledged the wisdom and necessity on grounds of policy and law, where a substantial difference of medical opinion was involved, of supplying some fixed, fair and objective standard by which all questions of uncertainty would be eliminated. The standard which the legislature chose is thus described by the Court in *Belmont Laboratories* v. *Federal Trade Commission*, 103 F. (2) 538, (3rd Circ.) p. 543, "*the test of truth was made the general agreement of medical opinion.*"

Where the assertion is of a therapeutic claim or opinion, there is, as this Court said in the *McAnnulty* case to which the Legislature referred, "no exact standard of absolute truth by which to prove the assertion false * *", 104, "no precise standard by which to measure the claims of either" 106, (*i. e.*, either of two opposing opinions); "The effectiveness of almost any particular method of treatment of

disease is, to a more or less extent, a fruitful source of difference of opinion, even though the great majority may be of one way of thinking", 105. Such an assertion is made in "a field of knowledge where even experts at times must be content with approximations to verity"; *Scientific Mfg. Co. vs. Federal Trade Commission*, 124 F. (2) 640, p. 644.

Even before the adoption of the Wheeler Lea Amendments it was held that a therapeutic claim could not be suppressed where there is "a substantial conflict of opinion on this subject". *L. B. Silver Co.* v. *Federal Trade Commission*, 289 Fed. 985, 990 (6th Cir.); accord *Raladam Co.* v. *F. T. C.*, 42 F. (2) 432, 435, requiring at least "a fair concensus of expert opinion," aff'd on other grounds 283 U. S. 643; and in *McLean Medicine Co.* v. *U. S.*, 253 Fed. 694 (8th Cir.), that "The testimony of the physicians as to their individual opinions of the efficacy of the preparation would have been properly rejected if there had been disclosed a difference of medical opinion on the subject" (696). As Mr. Justice Holmes observed in *U. S.* v. *Johnson*, 498, *supra*, it is unlikely that Congress would "distort the uses of its Constitutional power to establishing criteria in regions where opinions are far apart.". Since a trained and highly skilled physician versed in medical science is, as a matter of law, protected if he acts in accordance with respectable minority medical opinion where medical opinion is divided (*McHugh* v. *Audet*, 72 F. Supp. 394, 400, *Grudinski* v. *Lane* (Supreme Court of Washington) 30 P. (2) 970; *Blankenship* v. *Baptist Memorial Hospital* (Court of Appeals, Tenn.) 168 S. W. (2) 491), it is still less likely that Congress could have intended to impose a higher standard on laymen not similarly advantaged by scientific knowledge, training and profession. Apart from the present statute the necessity has long been legally established of supplying certain and objective standards of

scientific truth by requiring proof of "a general scientific recognition" (*People* v. *Forte*, 279 N. Y. 204, 206); "a general acceptance in the particular field to which it belongs" (*Frye* v. *U. S.*, 293 Fed. 1013; C. A. D. C., 1014) of the truth for evidentiary purposes of scientific tests, principles or devices. (*Medley* v. *U. S.*, 155 F. (2d) 857, 860 (C. A. D. C.); *People* v. *Morse*, 38 N. W. (2d) 322, Sup. Ct. Michigan.

Further evidence found in the legislative history shows that even where, contrary to the facts in this proceeding, the great body of qualified experts in that particular field regard the statement as "untrue" and the representations "*have only a narrow and limited support*" (House Report 2139), that is where "only a few experts regard" the "statement", "as true", *the utmost extent of the Commission's jurisdiction is to require a statement of the difference of opinion to be made in the advertising* (House Report No. 2139). *Under any circumstances, therefore, the Commission had no power to excise the word "Liver" from the product's trade name and the Court below was in error in enforcing the Order.*

Congress proposed the following provision which it later discarded as unnecessary because it was covered by the general prohibition against false advertising (House Report No. 1613 and Conference Report No. 1774 on the Wheeler-Lea Amendments), "Nothing in this paragraph shall be construed as requiring the making of such statement as to difference of opinion; and failure to so state the fact of such difference of opinion shall not relieve the Government of the burden of establishing the misleading character of the representation."

House Report 1613 on the Wheeler-Lea Amendments states:

> "It is to be noted that the difference of opinion involved is one existing at the time the advertisement

> is disseminated. Therefore, if it is necessary to establish in court the existence of such a difference of opinion, it will be done by testimony *as to the state of expert opinion on the question* at the time of the dissemination and not by testimony as to the state of expert opinion at the time of the trial *or by testimony of individual experts as to their opinion* regarding the truth of the representation. *There is no obligation on the advertiser to publish a statement that there is a difference of opinion as to the product he advertises. He may avail himself of such defense if he desires to do so.* Whether or not he does so does not relieve the government of carrying its burden of establishing the misleading character of the false advertisement."

A substantial difference in the status of medical opinion is thus made a *defense* to an assertion by the Commission of the falsity of a therapeutic claim and precludes it from finding that a cease and desist proceeding (15 U. S. C. 45) "would be to the interest of the public."

Compelling judicial interpretation of the Act is the decision of the Court of Appeals for the District of Columbia in *Alberty* v. *Federal Trade Commission*, 182 F. 2d 36, cert. den. 340 U. S. 818.

There the Commission and the Court found in substance that the therapeutic effect of a drug was recognized by *minority* medical opinion consisting of the homeopathic school, but rejected by the *majority* medical opinion, the allopathic school. In other words a conflict of medical opinion on the point was disclosed *where the majority opinion was opposed to the claim.* Seeking to compel the respondent there to disclose in its advertising this conflict of opinion, the Commission contended before the Court of Appeals (Brief p. 28, Record on Appeal) "There is no reason in law or logic why petitioners should be allowed to

advertise without restriction that the product is valuable when in fact it is valuable only in the opinion of a minority group". The Commission further contended (Brief, p. 26) that it was empowered by the statute to resolve this dispute and to issue a cease and desist order *whether experts of different schools or of the same schools were in disagreement.* The Court of Appeals rejected both of these contentions and held that the Commission was without power to issue a cease and desist order or to compel disclosure to be made in the advertising of this important majority medical dissent from the therapeutic value of respondent's claim. This Court denied the Commission's application for a writ of certiorari, 304 U. S. 818, 819.

If the Commission could not under the *Alberty* decision compel this qualification to be made, *a fortiori* under that decision it could not issue a cease and desist order.

The concurring opinion of Judge Healy in another case, *Alberty* v. *Federal Trade Commission*, 118 F. (2) 669 (9th Cir. 1941) 671, cert. den. 314 U. S. 630, is also a clear indication that the Commission has no authority under the Act to make an arbitrary choice with regard to the truth or falsity of therapeutic claims between conflicting segments of general medical opinion where such opinion is divided.

Aware of the deference which reviewing courts are impelled to pay to the "special competence" of administrative agencies, the Legislature properly recognized the greater necessity of providing some fair, certain, and objective standard for an administrative determination of the falsity of a therapeutic opinion, since otherwise the agency would become in practical effect the absolute and final arbiter of scientific truth immune from all effective judicial review. The standard was intended to provide a plain and understandable yardstick by which reviewing courts might test the correctness of the Commission's

determination, thus supplying the standard which the Court held was missing in the *McAnnulty* case.

The burden of proof of the falsity of Carter's therapeutic claim, which claim was asserted openly and without criticism or contradiction for three-fourths of a century, rested squarely on the Commission. Administrative Procedure Act, Title 5, U. S. C. Sec. 1006 (c). It must succeed, if at all, on the strength of its own proof—not on any supposed weakness in defendant's proof. *Oregon R. R. & M. Co.* v. *Fairchild*, 224 U. S. 510, 543.

It is Carter's position that the legislative standard of certainty in cases of such conflict requires, that the Commission *prove and find, as it has not done here,* that "general agreement of medical opinion" or consensus of medical opinion establishes the falsity of the therapeutic claim and the acceptability of the test procedures used in making that determination and that the existence of a substantial conflict in medical opinion is a defense to a cease and desist proceeding. Further, as a matter of expressed legislative policy, where the Commission has met such standard of proof and has also shown that the representations of therapeutic value "have only a narrow and limited support", which the Commission has not done here, the Commission's statutory jurisdiction *is at all events restricted to requiring a statement of the conflict of opinion to be made in the advertising.* Even prior to the Wheeler Lea Amendments this Court held that the Commission's power is restricted to "requiring proper qualifying words to be used in connection with the (trade) names". *Federal Trade Commission* v. *Milling Co.*, 288 U. S. 212, 217. As this Court held in *Siegel Co.* v. *F. T. C.*, 327 U. S. 608, 612, "the policy of the law to protect them (trade names) as assets of a business indicates that their destruction should

not be ordered if less drastic means will accomplish the same result.'"*

The Commission therefore was without power to enjoin the making of the claim and to prohibit the use of the word "Liver" in the trade name of the product. Its Order constitutes "agency action taken in excess of delegated powers." *Leedom* v. *Kyne*, 358 U. S. 184, 190.

B.

The Substantial Difference in Medical Opinion, Found by the Court of Appeals and Disclosed by the Record, Deprived the Commission of Power to Suppress the Claim.

The Commission's complaint tendered the issue—which Carter's answer denied—that *no* recognized body of medical opinion supported Carter's therapeutic claim that the drugs in its product increase the flow of bile (Vol. I, 16, 17). Such allegation was a recognition by the Commission of the burden and standard of proof imposed on the Commission by the Act. The Commission failed both to prove that allegation and to find that that allegation had been proved. The rule of recovery *secundum allegata* applies to the Commission. *Federal Trade Commission* v. *Gratz*, 253 U. S. 421, 427.

The Court below found that the record presented a conflict on this issue, saying (Opinion, Appendix, p. 51):

> "Our careful examination of the record demonstrates to us that the issue concerning 'general informed medical opinion on basic medical issues,' was not only a subject of comment appearing in vari-

* The Commission gave no consideration and made no determination (compare *Siegel Co.* v. *F. T. C.*, *supra*) *in the light of these express statements in the legislative history*, as to shaping of the remedy to permit the use of qualifying words or the notation of a difference of medical opinion in the advertising *because the Commission erroneously rejected all of Carter's contentions concerning the effect of the Wheeler-Lea amendments.*

ous professional opinions tendered by Carter's expert medical witnesses, but their opinions on this subject were countered by conflicting views expressed by Commission witnesses. From the tenor and purport of testimony offered by Carter's witnesses it is clear that such testimony was introduced to demonstrate the existence or non-existence of a substantial fact, i.e., whether there existed a 'consensus of informed medical opinion' which sustained the validity of Carter's advertising claims concerning the many therapeutic virtues of its medical preparation."

The Court regarded the conflict as a substantial one which it declared *its inability to resolve "in face of the fact that medical experts have reached different conclusions on this issue."* (Opinion, Appendix p. 52.)

The Commission, however, made *no finding* that the difference of medical opinion was not substantial or that the falsity of the therapeutic claim was established by the consensus of qualified medical opinion or by general medical agreement or by test methods so approved.* *Such findings by an administrative agency are jurisdictional and will not be implied. U. S.* v. *Chicago M. St. P. & P. R. Co.*, 294 U. S. 499, 504-5; *Atchison Ry.* v. *U. S.*, 295 U. S. 193, 202; *Secretary of Agriculture* v. *U. S.*, 347 U. S. 645, 654. "In the absence of a finding of essential basic facts, the order cannot be sustained". • • • the "lack of express finding by an administrative agency" may not be supplied by implication, *Atchison Ry. Co.* v. *U. S., supra*, 202. An omission to find is equivalent to an adverse finding, *Dektor* v. *Overbrook Nat. Bank of Philadelphia*, 77 F. (2) 491

* The same contentions made here and in the Court of Appeals regarding the effect of the Wheeler-Lea amendments were presented by Carter to the Commission prior to the latter's rendition of its final decision in this case. (Vol. XIV, Carter's Brief on appeal to the Commission, Point I.)

(3rd Cir.) 492; *Arizona Commercial Mining Co. v. Iron Cap Copper Co.*, 239 Pac. 290, cert. den. 270 U. S. 642; 64 C. J. Trial, Sec. 1079, p. 1236 and cases cited. There was thus a complete failure of both the *proof and finding* required by the Wheeler Lea Amendments and their legislative history. The Commission found only "that the greater weight of the testimony and other evidence introduced into the record supports informed determinations that the preparation Carter's Little Liver Pills will not stimulate the formation of bile by the liver or increase the secretion of bile by the liver" (Vol. V, 303).

Careful examination of the record* to which the lower Court referred above confirms that Court in its belief that the record developed a substantial difference in medical opinion and discloses also substantial clefts in qualified medical opinion as to the acceptability of the test methods used by the Commission to determine the effectiveness of the drugs and an entire absence of consensus of qualified medical opinion regarding every aspect of the standards employed in the tests. The Commission's Findings were based primarily upon these test methods (Findings, Vol. V, 278-286, 303).

Carter's expert witnesses, Doctors McGuigan (Vol. II, 925-927), Crandall (Vol. XI, 2883-8), Whiteleather (Vol. IV, 1640-1666) and Morrison (Vol. III, 1104-5) testified in effect that the experiments of the Commission's witnesses were not conducted in accordance with test procedures accepted by general medical agreement.

This substantial difference in medical opinion as to the acceptability of the test methods employed by the Commis-

* This Court will appreciate that an exhaustive review of this voluminous record on these issues cannot be made within the space limitations of this Petition for certiorari and that what follows is only a summary presentation of the extensive basic differences in medical opinion regarding this particular therapeutic claim of which the record presents many other instances.

sion to disprove Carter's basic therapeutic claim was not confined to a conflict between the respective testimony of the experts for Carter and of the experts for the Commission. On the contrary the Commission's principal expert witness, Dr. Ivy, admitted in an article published *ante litem motam* (Vol. VI, 684-685) that by the use of the surgical test method he employed to determine the therapeutic effect of the drugs "the physical conditions are entirely changed" and that there was produced thereby "a disturbance and possible creation of abnormal difference in pressure" (*id.* 684-685).

With regard to this same surgical test method, known as a bile fistula, the Commission's witness, Dr. Bollman, asserted, in a published article co-authored by himself and Dr. Mann, (Carter's Ex. 342, Part 21) that where such a "fistula has been made, characteristic atrophy of the liver occurs", and that "even the most important reported studies of the various competent investigators on the factors concerned in the formation and secretion of bile in animals with biliary fistula contain an astonishing amount of contradictory results and conclusions".

A vivid description of these fistula methods, which on its face precludes their acceptance by general medical agreement, is provided by paragraph 106 of the Examiner's Original Report (Vol. I) as supplemented by the record:

1. A tube was inserted from the outside through a hole cut in the dog's side and, by means of an incision, introduced into the duct leading from the gall bladder to the common duct which goes directly from the liver to the duodenum.

2. One whole inch was surgically excised from the animal's common bile duct.

3. The whole gall bladder was surgically removed in each case.

4. These animals were not anti-aseptically prepared, i.e., no antiseptics were administered to prevent the results, still further upsetting to their metabolisms of the growth and spread of infections from these drastic surgical operations.

5. The normal passage from the liver to the duodenum was severed surgically and the end nearest the duodenum closed up and "buried in the body tissue."

6. The other end of the severed duct was also closed up and buried.

7. Instead of the bile formed by the liver being allowed to follow its normal course, it was forced to back up and flow outside through the tube described above.

8. The bile was in some cases drawn out of the animals by suction artificially applied.

9. The animals survived but a few months and self-evidently started their own death processes the moment the operation was performed. They were given an over-dose of an anesthesia and disposed of.

10. Anaesthetics shown, and conceded, to have the effect of abolishing or interrupting the flow of bile were administered to them initially and in the short term experiments continuously throughout their whole performance.

Such variables and upsetting surgical operations as these were held to disqualify this type of experimental proof as a matter of law in *U. S. v. 50 Tubes*, 32 F. S. 958,

"The inherent sacredness of such experiments designed to prove a preconceived hypothesis is illustrated by the statement of the Court in *Vann v. Wright Lumber Co.*, 174 F. 2d 305 (10th Cir. 1949), that 'one is not allowed to change the conditions under which the experiment is made will-nilly at the peril as to wholly destroy its value as evidence.'"

p. 961 in a carefully considered opinion by the late Judge Woolsey to which this Court's attention is respectfully directed.

The expert witness for the Commission, Dr. Ivy, testified that the reaction time of these drugs required from 8 to 12 hours but conceded that in his principal animal tests he had continued the experiment for only 4 hours at the most (Vol. VI, 504; Commission's Ex. 98; 573; Vol. II, 630, 635; 638). As an indication, on the other hand of what a proper prolongation of such a test should be, the Commission's expert witness, Dr. C. Riegel, in testing the action of a similar type of drug in increasing bile flow had written an article placed in evidence as Carter's Ex. 108 A-D (Part 14) in which the test was prolonged for 12 hours after administering the drug.

In his tests to determine the effectiveness of these drugs, the Commission's witness, Dr. Ivy, administered concomitantly with the drugs large doses of bile salts, a known potent substance increasing bile flow (Vol. II, 591-2; 596), though, in criticising tests performed by Carter's experts, he had testified, "I would not try to determine the effectiveness of an unknown substance on the formation of the bile by the liver, or on the evacuation of bile from the gall bladder, or increasing the flow of bile into the duodenum by giving the unknown substance with a known potent substance. That, in my opinion, is a poor type of experimental design with which to test the activity or physiological or pharmacological action of any unknown substance" (Vol. IV, 1548).

Another key witness for the Commission, Dr. Bollman, had published an article—again *ante litem motam*—in which he declared that the value or acceptability of a liver function test employed by the Commission's witness, Dr. Ivy, to test the drugs *on animals* could only be determined by careful and controlled observations *on the human being*

(which was not done here) because it had been found that the test in species of different animals varied considerably (Carter's Ex. 342, Part 21).

Bollman himself in his own tests made only a gross—that is a non-microscopic test—by manually feeling the livers of his three test dogs "after", as the lower Court said in its prior opinion in this case (201 F. 2d p. 450) "varying degrees of post-mortem degeneration had taken place", though in a previously published article which he endorsed as still correct he gave it as his view that such a gross examination does "not give accurate information with regard to the degree of physiologic change" (Vol. X, 2576-7).

That medical science has as yet failed to develop adequate tests to measure the functioning of the liver was established out of the mouth of the Commission's witness, Dr. Bollman. This expert witness for the Commission had published his considered view, and on the rehearing after remand agreed that it substantially represented his view today, that "as the liver has so many important functions, it would seem easy to elaborate a method of measuring when normal and when diseased at least one of these functions. This has not been possible up to the present time" (Vol. XII, 3273, 3294; Carter's Ex. 342, Part 21) and that "the ideal method of determining experimentally the value of any functional test would be to employ it in an animal with a pathological condition identical with that found in man. This ideal condition has rarely been approached with regard to any organ, *and certainly not with the liver.*"**** "There appears to be no physiologic basis for many of the tests employed to measure the functional capacity of the liver" (*Id.*). Bollman's statements give support to those of Carter's witness, Dr. Killian, in Commission's Ex. 181 A-J (Part 15), put in evidence by the Commission itself,

that "the fact that the bile acid metabolism is at present obscure and confusing must be admitted in any review on the subject. The literature, with several notable exceptions, is contradictory, fairly profuse and unconvincing. Furthermore, the multitude of methods for the determination of these bile constituents renders the comparison of the results of different investigations difficult" * * *, and to those of Carter's expert witness, Dr. Hazelton (Commission's Ex. 122A, Part 14) "Every few years see new tests of function of the liver come and go and have their day during the ebb and tide of scientific popularity", and (Commission's Ex. 123-A, Part 14) "It is generally conceded that currently employed liver function tests still leave much to be desired as an accurate index of the function of the liver".

Dr. Bollman made only a single test on only *three* dogs, though the Commission's witness, Dr. Ivy, stated (Commission's Ex. 97) that "Even under the best conditions of methodology and control of diet, variations occur which can only be smoothed out by the performance of a number of tests either on the same or on a group of different animals", and although the Commission's witness, Dr. Carlson, had published his view concerning the danger of conclusions based on insufficiently representative tests that "perhaps by accident the few dogs employed were not representative of dogs in general" (Vol. V, 42-43).

The Commission's witness, Dr. Bollman, admitted (Vol. IV, 1474-7) that there was no condition in man which corresponded to the abnormal surgical condition of obstipation which he had produced in the dogs he experimented on, and this defect in the medical acceptability in his test procedures was confirmed by Carter's expert, Dr. Crandall (Vol. XI, 2883). The Hearing Examiner conceded that it had been developed by Bollman's cross examination "that there was no satisfactory

demonstration of adequate liver function on the part of these three dogs prior to the conduct of these experiments" (Vol. XII, 3256-7; 3300). Yet the Commission rejected the experiments of Carter's witness, Dr. Morrison (Vol. V, 300), for similar lack of proper controls. The Commission's witness, Dr. Bollman, conceded that the possibility was not excluded of a connection between some function of the liver and the physiological processes which cause constipation (Vol. XII, 3259); yet all the experiments of Carter's expert, Dr. Killian, were condemned by the Commission as "inconclusive" (Vol. V, 301, 302, 317). In other words the dual standard of conclusiveness was applied by the Commission to Carter's tests alone. The Commission's witness, Dr. Ivy, conceded that bile "normally flows into our intestines, and in the experiment in Table I (Commission's Ex. 97) there was no bile in the intestine * * *" (Vol. II, 591). Yet the Commission excluded Carter's offer of proof by accepted medical texts (Carter's Exhibit for Identification No. 7) that studies made by Ivy's surgical fistula bile method "can hardly be considered normal" and disregarded the testimony to the same effect of Carter's expert, Dr. Morrison (Vol. III, 1104-5).

None of the tests upon which the Commission placed its determination were subjected to statistical analysis necessary to determine their significance,* although the Commission's witness, Dr. Carlson, had published his view in a treatise excluded by the Hearing Examiner and the Commission (Vol. V, 45) that "Special mathematical techniques employed in statistics may be required to determine whether the difference observed in the experimental

*See discussion of the necessity for evidentiary purposes for statistical check of the significance of experiments in the well considered article by Judge Pope of the San Antonio Court of Civil Appeals, entitled "Presentation of Scientific Evidence", 31 Texas Law Review 1953, June p. 794.

and controlled group are probably significant or probably due to chance", and although the Commission's witness, Dr. Bollman, testified that "I usually ask a statistician to determine the significance of the data which I supply him on a statistical basis" (Vol. IV, 1486).

The admissions of the Commission's own experts, therefore, disclosed on their face an absence of general medical agreement regarding the adequacy or acceptability of the test methods used by the Commission in its determination of the falsity of the therapeutic claim.

Every medical topic in this case is, further, at the very least, highly unsettled and controversial exhibiting not only an entire lack of general medical agreement but an actual **absence of scientific knowledge. The Hearing Examiner** found that "the liver is one of the most complex organs of the body", and "is the only organ of the body whose removal causes death and which cannot be explained by medical science at the present time" (Original Report paragraph 37 H; Vol. I, 63). "Little is known", the Examiner found (Original Report par. 41 L; *id.*, 65) "as to whether or not the liver produces all of the remaining proteins of the blood plasma". The liver has about one hundred activities (Commission's witness Dr. Ivy, (Vol. VI, 474). The "question is not settled" whether the bile salts "are made by the liver" (Carter's Ex. 342, article by the Commission's witness, Dr. Bollman). "The amount of bilirubin formed and the rate at which it forms depend on several factors, some of which are unknown." (Bollman, same Ex.). "Only one function is definitely known for bile salts, that of assisting in the digestion of fats. Little is known as to the origin or precursor of cholic acid and little is known as to the products of its destruction in the body" (Bollman same Ex.). "There is no evidence available which would indicate the presence or absence of a

common factor in the various injuries to the liver produced by disease, hepatotoxic agents or dietary deficiencies" (*id.*, Bollman, Carter's Ex. 346). "We know a few things about experimental pathology of the liver, but there are a great many things still in the realm of the unknown" (Bollman, Carter's Ex. 348). The extent to which the liver's functions are unsettled medically is again reflected in the testimony of the Commission's witness Dr. Carlson (Vol. I, 370) that "The role of the vagi nerves" going to the sphincter of Oddi "on the reflex control of the system is pretty much in doubt"; and there are probably other functions of the liver (Vol. V, 365) "that are not yet discovered". "It is not certain yet whether that choline is the same hormone which is created as one of the hormones by the pancreas"; (Carlson, *id.* 367) "all of these we do not quite understand." "Very little is known or understood concerning the fluctuations of bile acids in pathological conditions" (Commission's Ex. 181-E, article by Carter's expert witness, Dr. Killian). Commission's Ex. 121-A states that in the last one hundred and fifty years "there has not been a satisfactory method for the clinician in the practice of medicine to utilize the facts unearthed by innumerable investigators relating to the function of the liver in health and disease" (article by Carter's expert witness, Dr. Morrison). The Commission's Exhibit 97, an article written by the Commission's witness Dr. Ivy, states "* * * the literature on the effect of aloes and podophyllum on bile formation is contradictory" and emphasizes "the uncertain state of the literature regarding the effect of aloes or podophyllum on bile formation", and the Commission in its Opinion concedes, (Vol. V, 318), "It is true that the results of experiments reported in the scientific literature dealing with the effects exerted by aloes and podophyllum have presented some conflict." "Intravenous

injection of extract of aloe increases the flow of bile in the anaesthetized dog * * *. Intravenous injection of resin of podophyllum increases the flow of hepatic bile in the anaesthetized dog" (Commission's Ex. 14, article by Carter's expert witness, Dr. Hazelton). Belief by medical practitioners in the efficacy of these drugs in increasing bile flow was testified to by the Commission's witness Dr. Palmer (Vol. II, 696) though he disputed the correctness of such belief. Published statements in a treatise by Dr. Martin Rehfuss, recognized as an authority by the Commission's witness, Dr. Bollman (Carter's Offer of Proof, Vol. V, Carter's Exs. 8 and 9 for Identification, excluded by the Examiner and Commission), are to the effect that the action of podophyllum "is to empty the liver radicles and fill the biliary passages * * * We have used all these substances." The Commission's witness Dr. Palmer also conceded in regard to one of the most vital issues in this suit, namely, as to whether there are certain conditions of the liver which Carter contends are improved by a better flow of bile, that there is a "difference of medical opinion" (Vol. VI, 651-653). Asked if his answer would not presuppose that there was an opinion contrary to his, the Commission's witness, Dr. Bollman, answered that he supposed "there are other views on the subject" (Vol. XII, 3173).

The Commission's witness, Dr. Ivy, had published articles (Vol. XII, 3198), which confirmed one of the basic aspects of Carter's therapeutic claim, to the effect that "lack of bile salts would increase the tendency toward constipation" and that "constipation may promote gall bladder or biliary tract stasis" (Vol. 3202-3), a view which was confirmed by the view of another text authority recognized as such by the Commission's witness, Dr. Bollman (Vol. XII, 3208-10) to the effect that "Deficiency of whole bile

or bile salts leads to constipation by interference with the water balance of the colon" (Vol. XII, 3209). Carter's witness, Dr. McGuigan (Vol. VI, 845-7) testified that it was the consensus of modern enlightened members of the medical profession that constipation lessens the flow of bile. This view was confirmed by textual statements of the English medical authority, Sir Humphrey Rolleston, recognized as such by the Commissioner's witness Dr. Bollman (Carter's Ex. for Identification 337, Vol. XII, 3222, 3224), that constipation is a causal factor in bilousness. Similar views were expressed by Carter's expert witnesses, Drs. Bastedo (Transcript 8802), Crandall (Vol. XI, 2906, 2919-20) and Morrison (Vol. VIII, 1571-1572).

Another important substantial conflict in medical opinion concerned the reliability of the so-called duodenal drainage methods used by Carter's expert, Dr. Killian, which were subjected by the Commission to the unlawful standard of conclusiveness, and rejected on that basis. Their medical acceptability was attested to by Carter's experts, Drs. Killian and Morrison (Vol. I, 171; Vol. VII, 998), and by a wealth of accredited textual medical authority included in Carter's offers of proof (Vol. V, 57-65) and excluded by the Commission, although it accepted hearsay evidence to support its witness, Dr. Case (Commission's Op., Vol. V, 321). The Commission's witness, Dr. Bollman, conceded that quantitative determinations could be made by that method (Vol. IV, 1435).

The same basic difference in medical opinion which prevailed with respect to these issues, prevailed also with regard to the crucial question of the precise conditions under which the results of the Commission's experiments with drugs on animals could be transferred to man. For example, the Commission's witness, Dr. Carlson, testified (Vol. II, 486) "If you find, for example, that a rat doesn't

need Vitamin C in the diet for its health and life, it doesn't follow that other animals do not need Vitamin C." The 1949 Annual Report, Federal Security Agency, Food and Drug Administration, p. 45, states that "Analytical methods that depend on the reaction of laboratory *animals* for the determination of the potency of drugs are laborious, time consuming, and *relatively inaccurate*". Carter's offer to show that it is the practice of the Federal Food and Drug Administration to require animal tests to be supplemented by tests on humans because of the "varying reactions to the same drugs from different species of animals" (Vol. V, 41-42) was rejected (Vol. V, 139-140). Carter's efforts to examine its witness, Dr. Crandall, on this point met with this fate:

> "By Mr. Hanaway:
>
> "Q. Mr. Cohn asked you some questions about the knowledge which had been attained by the medical profession concerning biliary tract as a result of studies made on animals, and particularly dogs. Do all drugs act therapeutically in the same manner and to the same degree when administered to dogs and man on an equivalent weight basis?"
>
> "Mr. Cohn: I object to that.
> "Trial Examiner Purcell: Off the record."
>
> "(Discussion off the record.)"
>
> "Trial Examiner Purcell: On the record. Let the record show that the *objection is sustained*" (Crandall, Vol. XI, 2923).

The undisputed testimony of Carter's witness, Dr. Hazelton (Hazelton, Vol. VI, 789), that "the generality in that regard is that dogs, or rats, or mice, or other *animals generally require a much larger dose per unit of body weight than the human does*", was ignored and unmentioned

by both Examiner and Commission. An article co-authored by the Commission's witness, Dr. Ivy, entitled "The Response of the Canine and Human Pancreas to Secretin" (Carter's E. 312 A to N) indicates clearly the varying responses of dog and man regarding dosages of the same drug. "It is possible that these variable results may be explained on a basis of *dosage;* relatively small doses per kilo such as are given *in man* cause the production of a comparatively small amount of juice relatively rich in enzymes, while the injection of larger doses, *as in the dog*, cause the secretion of an abundant gastric juice *poor in enzymes.*"

Dr. Ivy testified that the functional activity of dog and man was at least known "to vary *significantly* in one respect and that is as to the metabolism of uric acid." This was further confirmed by the Commission's witness Dr. Bollman, who testified (Vol. IV 1382) that "the dog's liver destroys uric acid. Ordinarily that is taken to be quite a difference between that and man * * *." "That in comparison is just one exception, one thing you would have to know in order to compare the results of animal experimentation with that of the human." Bollman testified (Vol. IV 1442) that the dog and the human also differed in regard to the presence or absence under certain circumstances of bilirubin, another product of the liver, in the blood. Dr. Bollman testified on the rehearings (Vol. XII 3297-8) that he was still of the view today expressed in his previously published paper that "We do not feel justified in attempting to interpret our observations of jaundiced *dogs* in relation to the occurrence of peptic ulcer in *man.*" Bollman (Carter's Ex. 342) had published an article stating "The value of the direct and indirect Vandenbergh tests, as differential diagnostic tests *can be determined only by careful and controlled observations on the human being, because we have found that the test in*

species of different animals differs considerably. Carter's witness, Dr. Killian, wrote (Commission's Ex. 181 A-J) "Methods based on the sulphur content in whole bile or urine may be applicable in the case of the *dog* where mainly taurocholic acid is excreted, but even there, etherial sulphates and sulphur containing phosphatides may afford serious interference. *In humans the method is completely inapplicable.*" In a published article by Carter's witness Dr. Morrison, and William A. Swalm (Commission's Ex. 121A) it is said with regard to a certain test "as pointed out by Sobotka and especially by Doubilet, it is specific for cholic acid alone and is of little value in the analysis of *human* bile which contains a large proportion of desoxycholic acid".

The closeness of the issue and the substantiality of the difference of medical opinion on all these basic questions are further attested to by the immense volume of expert testimony in that regard and by the fact that the Commission deliberated for five years after the case was originally submitted to it for decision before it resolved that issue, took a number of months to reconsider and decide it after the remand, and by the fact that the Court below held the case *sub judice* for nearly a year and a half before rendering its decision.

Had it been possible for the Commission to *find* that the falsity of Carter's basic therapeutic claim had been established *by general medical agreement* or by consensus of medical opinion or by test methods so approved, it is obvious that the Commission would have done so, particularly in view of the fact that Carter's Brief to the Commission (Vol. XIV) raised its present contentions regarding the effect of the Wheeler-Lea Amendments. Precision in an administrative agency's *quasi* jurisdictional findings —lacking here—is required by this Court's decisions in

Secretary of Agriculture v. *U. S.*, 347 U. S. 645, 654 and *Automatic Canteen Co.* v. *Federal Trade Commission*, *supra*. The best evidence that it was not possible to make such a *finding* is the fact that none was made. Even if it had been possible—and it was not—"The Commission's action cannot be upheld merely because findings might have been made and considerations disclosed which would justify its order. * * * There must be such a responsible finding." *Securities Commission* v. *Chenery Corp.*, 318 U. S. 80, 94.

This case therefore involves "a subject which is on a hitherto unsettled frontier of the art of medicine" (*U. S.* v. *59 Tubes etc.*, 32 F. Supp. 958, 962; Opinion by the late Judge Woolsey) involving questions as to the adequacy and acceptability of the test procedures under general medical opinion and as to whether the methods employed in testing the drugs did not "so upset the metabolism or physiological reactions of the animals as to make a serious difference in the tests made on them", the "juridical effect" of which was to compel their rejection (961-962). There were involved just such "differences of opinion among the experts as to the acceptability of various test procedures" which led the Commission to dismiss its complaint in the *Lambert Pharmacal* case, *supra*.

There was *not* involved, as this Court found in its opinion in *Reilly* v. *Pinkus*, 338 U. S. 269, a conflict in medical opinion which was only slight. On the contrary the test methods used to determine the issue of the truth of this specific therapeutic claim concerned, as this Court said in *Reilly* v. *Pinkus*, 274, "medical practices in fields where knowledge has not yet crystalized in the crucible of experience", and required—even apart from statutory and constitutional standards—" an evaluation based on a disinterested inquiry pursued in the spirit of science". *Rochin* v.

California, 342 U. S. 165, 172. Such an evaluation was not made and it was neither proved nor found that the falsity of the therapeutic claim had been established by general medical agreement. There was thus a failure to comply with the standard of proof required by the Act.

C.

The Lower Court Failed to Perform Its Duties as a Reviewing Court by Neglecting to Pass Specifically or Adequately on the Issue of Denial of Procedural Due Process and the Essential Unfairness of the Commission's Standards of Proof.

It is a further aspect of Carter's contention with regard to the special standard of proof of the falsity of therapeutic claims imposed by the Act that there is implicit in the Act and explicit in this Court's decision in *Automatic Canteen Co.* v. *Federal Trade Commission*, 346 U. S. 61, 81 a requirement of "essential fairness" in the standards which the Commission applies in reaching its conclusions, and that the lower Court erroneously failed to pass upon Carter's specific showing that there was a lack of such essential fairness in the instant case. There has been no adequate review by the Court of Appeals of "the correctness of the standards which the Commission applies and the essential fairness of the mode by which it reaches its conclusions". *Automatic Canteen Co.* v. *F. T. C.*, *supra* 81.

The essential unfairness and duality of the standards used by the Commission in appraising its own and in rejecting Carter's experimental proof, on which the Court below failed specifically to pass, some of which have been previously noted in subheading B above, are further illustrated by the following typical examples taken at random from a host of others.

As to a liver function test—performed by the Commission's witness, Dr. Bollman, in testing the drugs on three dogs, accepted without criticism by the Commission, Bollman himself conceded (Vol. IV, 1382) that it was a sensitive test "with the qualification that the gall bladder is removed at the same time." He was asked and answered "Q. Was the gall bladder removed in any of the three dogs? A. No." (*Id.* 1384). Obviously, this was a negation of his test methods' conformity to general medical acceptability. Asked whether another test used and accepted without question by the Commission was not designed for diagnostic and functional purposes rather than for quantitatively measuring increases in the flow of bile, the Commission's key witness, Dr. Case, answered "Diagnostic and functional purposes" (Vol. XI, 3023). Carter's tests were, on the other hand, rejected by the Commission (Vol. V, 301, Findings Paragraph Thirteen) for that very reason, namely that they were designed for diagnostic and functional purposes but not for quantitative measurement.

Tests of the action of the drugs by Carter's principal witness, Dr. Killian, were rejected by the Commission as "inconclusive" because of his use concomitantly of peptone, a recognized stimulant to bile flow regarded by the Commission as an upsetting variable (Vol. V, 296, Findings, Paragraph Eleventh) while similar to its performance by the Commission's witnesses Drs. Ivy and Case were accepted without criticism though similar potent bile stimulants were likewise concomitantly used (Vol. II, 591-2; 596; Vol. I, 94, 96; Vol. XI, 3094). Thrice in its Findings (Vol. V, 300, 301, 302) and twice in its Opinion (Vol. V, 317, 318) the Commission subjected Carter's proof *alone* to the unlawful requirement of *conclusiveness*, though as the Court held in *Thompson Lumber Co.* v. *Interstate Commerce Commission*, 193 Fed. 682, the Commission "had no right

to array itself against that which was produced, to the extent of holding that it was not conclusive; which was in effect saying that nothing short of what was incontrovertible would satisfy it." (684). On the other hand, the Commission neither subjected its *own* proof to the same requirement of *conclusiveness* nor did it find its *own* proof *conclusive*.

All of the testimony of Carter's witness, Dr. Morrison, was discredited by the Commission on the ground that his test subjects "also received vitamin pills", "or were on a special nutritious diet" (Vol. V, 300, Findings, Paragraph Thirteen), while the dog tests of the Commission's witness Dr. Bollman, were accepted although they were placed on a highly protective carbohydrate diet which in a prior publication he had conceded minimized the effect on the liver which his experiments were designed to test (Vol. XII, 3330-24, 3354). The testimony of Carter's witness, Dr. Morrison, was discredited because he failed to tell his experimentees that they were being administered doses of Carter's Little Liver Pills and received pay for the treatment (Vol. V, 300); while, on the other hand, the testimony of the Commission's witness, Dr. Case, was accepted without criticism although he testified that he pursued precisely the same practice (Vol. VI, 513).

The Commission received hear-say evidence to bolster the testimony and tests of its expert witness, Dr. Case (Commission's Opinion, Vol. V, 321) but rejected or ignored evidence proffered by Carter of admissions by the Commission's witness which discredited their test procedures.

"Fair play" "is the essence of due process." *Galvan v. Press*, 347 U. S. 522, 530. "The parties should contend on an equal field, and be allowed to use the same weapons." *Corning v. Burden*, 56 U. S. 252, 271.

The unfairness and duality of these standards and other specific instances of plain denials of due process (of which space restrictions imposed on petitions for certiorari prevent an adequate presentation here) were strenuously urged and carefully documented by reference to the Record in Carter's Briefs in the Court of Appeals. This Court will be surprised to learn, therefore, that the lower Court failed specifically or adequately to pass upon these specific objections concerning the unfairness of the standards of proof used by the Commission in arriving at its Findings. Such extraordinary procedure violates the rule, which early in its history this Court laid down, that "where the law gives a party an appeal, he has the right to demand the conscientious judgment of the appellate Court on every question arising in the cause." *Post v. Jones*, 60 U. S. 150, 160. The lower Court has, therefore, "so far departed from the accepted and usual course of judicial proceedings" "as to call for an exercise of this Court's power of supervision" under Rule 19 governing writs of certiorari.

Conclusion and Relief Requested.

The issue is far too important to leave to a summary disposition by a mere parenthetic judicial statement of disagreement without the assignment of reasons by the lower Court for its rejection of Carter's contentions concerning the effect of the Wheeler Lea Amendments. Its action in so doing was a violation of "the duty of such courts fully to state the grounds upon which they act." *Beaumont, S. L. & W. Ry. Co. v. U. S.*, 282 U. S. 74, 86. The Opinion of the Court below indicates further miscomprehension of the issue. The statement quoted above from the Court's Opinion would seem to indicate that the Court felt that the burden was upon Carter to establish the truth of its claim

by consensus of medical opinion. Other passages in the Opinion would indicate that the Court interpreted Carter's contention as denying that proof of consensus of medical opinion involved proof of a fact, whereas that contention is that there is involved *proof and finding* of a special kind of fact which the legislative history shows requires a particular standard of proof. The lower Court's decision is in conflict with that of the Third Circuit in *Belmont Laboratories* v. *Federal Trade Commission*, 103 F. (2) 538, 543, *supra* which is the only reported case in which the legislative history of the Wheeler Lea Amendments has been judicially considered. The Findings of the Commission concerning the extent of the conflict in medical opinion lack the precision which this Court's decisions, above cited, require, and both proof and findings fail to conform to the requirements of the Wheeler-Lea Amendments to the Act. "Something more precise is requisite in the quasi-jurisdictional findings of an administrative agency". *Secretary of Agriculture* v. *U. S.*, 347 U. S. 645, 654. The essential unfairness of the Commission's dual standards has not been adequately passed on by the lower Court. The record discloses not only a substantial conflict in the status of informed medical opinion on the basic medical issues involved but also that the functioning of the liver presents a highly controversial and unsolved medical problem with regard to many aspects of which "medical opinion is yet in a state of flux." *Reilly* v. *Pinkus*, *supra*, 274.

The effect of these amendments to the Federal Trade Commission Act in the light of their legislative history has never been decided by this Court. The question of their effect as prohibiting in such a case as this a cease and desist order altogether or in any event confining the order to a requirement of qualifying words or of disclosure in the advertising of the difference in medical opinion is of

general public importance regarding the administration of the Act whose settlement the Commission should itself welcome rather than oppose. At a time when the nation is locked in a struggle with the forces of Communist science the issue of scientific freedom implicit in this case has larger implications than the fate of a particular proprietary preparation. Medicine is an applied science, and medical ideas find their embodiment and their incentive, "their spur of progress", (*Reilly* v. *Pinkus*) in practical applications, in the production of physical devices, apparatus, drugs and pharmaceutical products. Unless therapeutic claims are made without danger of unwarranted administrative censorship or suppression, drugs are not sold, medical advances are not tested in the market place and the public is deprived of new ideas and remedies. This Court has now extended even to *businesses* the protection of the provision against the unconstitutional abridgement of free speech; *Joseph Burstyn, Inc.* v. *Wilson*, 343 U. S. 495. In such cases "* * * the First Amendment's basic guarantee is of freedom to advocate ideas." * * * Its guarantee is not confined to the expression of ideas that are conventional *or shared by a majority*". *Kingsley International Pictures Corp.* v. *The Regents of the University of the State of New York*, 360 U. S. 684. Most certainly its guarantee extends to what is most important in a scientific age—scientific ideas. As this Court said in *62 Cases of Jam* v. *U. S.*, 340 U. S. 593, 600: "In our anxiety to effectuate the Congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop." Important as it is that the public be not duped, it is at least as vital that it be not deprived of medical ideas and therapeutic remedies and products by an administrative censorship that determines scientific truth

by fiat where scientists themselves are in wide disagreement.

For these reasons it is respectfully requested that:

(a) the writ of certiorari be granted and the judgment and decision of the Court of Appeals be reversed in so far as it affirms these provisions of the Commission's Order and the Commission's Order modified by excising therefrom the provisions in question (*Federal Trade Commission* v. *Curtis Co.*, 260 U. S. 568, 580); or,

(b) in the alternative, should this Court be unwilling either itself to determine whether or not there exists a substantial difference of medical opinion on the issues in question (*Hammond* v. *Schoppi Bus Line*, 275 U. S. 164, 171, 172) or to accept the lower Court's Opinion as a finding of such a substantial difference in medical opinion, or if this Court is in doubt as to the existence of such a substantial difference of opinion or the extent of that difference, then that this Court direct that the case be remanded to the Court of Appeals to make or to cause the Commission to make such determination (*Railroad Commission* v. *Maxcy*, 281 U. S. 82, 83) with instructions to the Court of Appeals, if on final review it finds that such a substantial difference of opinion exists, to set aside the provisions in question of the Commission's Order, or, if the Court below ultimately finds the difference of opinion to be slight then that the Commission's Order excising the word "Liver" from the product's trade name be set aside and the Order be confined to a direction that disclosure be made of the difference of opinion in Carter's advertising or by other qualifying words, and that the lower Court be instructed to pass

specifically on Carter's specific contentions regarding the essential unfairness of the standards employed by the Commission, and the defects in the test methods used by the Commission's witnesses, in reaching its conclusions.

Dated: August 27, 1959.

Respectfully submitted,

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APPENDIX.

A.

Decree of the Court of Appeals, Entered July 28, 1959.

DECREE APPROVED

H /s/ WILLIAM HEALY

B /s/ HOMER T. BONE

HA /s/ FREDERICK G. HAMLEY

Circuit Judges

(ENDORSED) Filed and Entered:
July 28, 1959

PAUL P. O'BRIEN, Clerk

UNITED STATES COURT OF APPEALS,

FOR THE NINTH CIRCUIT.

CARTER PRODUCTS, INC.,
Petitioner,
v.
FEDERAL TRADE COMMISSION,
Respondent.

No. 15373

Final Decree Affirming and Enforcing Order to Cease and Desist.

This Court in the original review of this matter, No. 12540, *Carter Products, Inc.* v. *Federal Trade Commission*, 201 F. 2d 446, having vacated and set aside the order to cease and desist issued against Carter Products, Inc., on the 25th day of March, 1951, by the Federal Trade Com-

mission, in a proceeding before it entitled "In the Matter of Carter Products, Inc., a corporation and Street & Finney, a corporation, Docket No. 4970"; and on certiorari the Supreme Court of the United States having on the 12th day of October, 1953, vacated the judgment of this Court and remanded the cause to this Court ". . . with directions to reinstate [our] prior judgment and order after amending it so that it specifically authorizes the Federal Trade Commission to open this proceeding for further evidence and a new order consistent with . . ." our aforesaid opinion, 346 U. S. 327; and this Court having, on the 18th day of November, 1953, entered judgment as directed by the Supreme Court, remanded the cause to the Federal Trade Commission with authorization "to open this proceeding for further evidence and a new order consistent with . . ." our aforesaid opinion; and the Federal Trade Commission having, on the 18th day of December, 1953, opened the proceeding ". . . for such further proceedings as may be necessary to correct the errors in the original hearings as specified by . . ." this Court in its aforesaid opinion; and the Commission having fully complied with the mandate of this Court by opening the proceeding, conducting further hearings in accordance with our remand order; and, at the conclusion of such hearings, the Commission having examined the record made in the original proceeding and the record made in the proceeding on remand, and having, on the 4th day of October, 1956, made its formal Decision, along with an entirely new set of Findings of Fact and Conclusions and, on the basis thereof, having issued a new Cease and Desist Order against Carter Products, Inc.; and Carter Products, Inc., having filed on the 30th day of November, 1957, a petition for review and to set aside this new order entered against it by the Commission; and the Commission having thereafter certified and filed, as required by the Federal Trade Commission Act, a transcript of the entire record in the original proceeding (No. 12940) and a transcript of the entire record in the proceeding on remand, upon which the new order to cease and desist is based; and the matter having been heard

by this Court on briefs and oral arguments, and this Court having thereafter fully considered the entire record and having rendered its decision on the 16th day of June, 1959, denying the petition to reverse and set aside the order of the Commission, issued on the 4th day of October, 1956, as aforesaid, and affirming and commanding obedience to the terms thereof;

NOW, THEREFORE, IT IS HEREBY ORDERED, ADJUDGED AND DECREED that the aforesaid petition of Carter Products, Inc., to reverse and set aside the order of the Federal Trade Commission be, and it hereby is, denied; and

IT IS HEREBY FURTHER ORDERED, ADJUDGED AND DECREED that the aforesaid order to cease and desist be, and it hereby is, affirmed; that petitioner be, and it hereby is, ordered to obey the terms of the said order to cease and desist and to comply therewith.

Without prejudice to the right of the United States, as provided in Section 5(1) of the Federal Trade Commission Act, to prosecute suits to recover civil penalties for violation of the aforesaid order to cease and desist, hereby affirmed and enforced, this Court retains jurisdiction of this cause to enter such further orders herein from time to time as may become necessary effectively to enforce compliance in every respect with this decree and to prevent evasion thereof.

By the Court:

.....

.....

.....

United States Circuit Judges

Dated:

APPENDIX.

B.

Applicable Provisions of The Federal Trade Commission Act As Amended By The Wheeler Lea Amendments, Being Respectively Sections 45, 52 to 58 of Title 15 U. S. C.

45. Unfair Methods of Competition Unlawful; Prevention by Commission—Declaration of Unlawfulness; Power to Prohibit Unfair Practices.

(a) (1) Unfair methods of competition in commerce, and unfair or deceptive acts or practices in commerce, are declared unlawful.

* * * * * *

(6) The Commission is empowered and directed to prevent persons, partnerships, or corporations, except banks, common carriers subject to the Acts to regulate commerce, air carriers and foreign air carriers subject to the Federal Aviation Act of 1958, and persons, partnerships, or corporations insofar as they are subject to the Packers and Stockyards Act, 1921, as amended, except as provided in section 227(b) of Title 7, from using unfair methods of competition in commerce and unfair or deceptive acts or practices in commerce.

Proceeding by Commission; Modifying and Setting Aside Orders.

(b) Whenever the Commission shall have reason to believe that any such person, partnership, or corporation has been or is using any unfair method of competition or unfair or deceptive act or practice in commerce, and if it shall appear to the Commission that a proceeding by it in respect thereof would be to the interest of the public, it shall issue and serve upon such person, partnership, or corporation a complaint stating its charges in that respect and contain-

ing a notice of a hearing upon a day and at a place therein fixed at least thirty days after the service of said complaint. The person, partnership, or corporation so complained of shall have the right to appear at the place and time so fixed and show cause why an order should not be entered by the Commission requiring such person, partnership, or corporation to cease and desist from the violation of the law so charged in said complaint. Any person, partnership, or corporation may make application, and upon good cause as shown may be allowed by the Commission to intervene and appear in said proceeding by counsel or in person. The testimony in any such proceeding shall be reduced to writing and filed in the office of the Commission. If upon such hearing the Commission shall be of the opinion that the method of competition or the act or practice in question is prohibited by sections 41 46 and 47 58 of this title, it shall make a report in writing in which it shall state its findings as to the facts and shall issue and cause to be served on such person, partnership, or corporation an order requiring such person, partnership, or corporation to cease and desist from using such method of competition or such act or practice.

* * * * * *

REVIEW OF ORDER; REHEARING, &c.

(c) Any person, partnership, or corporation required by an order of the Commission to cease and desist from using any method of competition or act or practice may obtain a review of such order in the court of appeals of the United States, within any circuit where the method of competition or the act or practice in question was used or where such person, partnership, or corporation resides or carries on business, by filing in the court, within sixty days from the date of the service of such order, a written petition praying that the order of the Commission be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Commission, and thereupon the Commission shall file in the court the record in the proceeding,

as provided in section 2112 of title 28. Upon such filing of the petition the court shall have jurisdiction of the proceeding and of the question determined therein concurrently with the Commission until the filing of the record and shall have power to make and enter a decree affirming, modifying, or setting aside the order of the Commission, and enforcing the same to the extent that such order is affirmed and to issue such writs as are ancillary to its jurisdiction or are necessary in its judgment to prevent injury to the public or to competitors pendente lite. The findings of the Commission as to the facts, if supported by evidence, shall be conclusive.

* * * * * *

52. Dissemination of False Advertisements—Unlawfulness.

(a) It shall be unlawful for any person, partnership, or corporation to disseminate, or cause to be disseminated, any false advertisement

(1) By United States mails, or in commerce, by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics; or

(2) By any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase in commerce of food, drugs, devices, or cosmetics.

Unfair or Deceptive Act or Practice.

(b) The dissemination or the causing to be disseminated of any false advertisement within the provisions of subsection (a) of this section shall be an unfair or deceptive act or practice in commerce within the meaning of section 45 of this title Sept. 26, 1914, c. 311, § 12, as added Mar. 21, 1938, c. 49, § 4, 52 Stat. 114.

§53. SAME; TEMPORARY INJUNCTION—POWER OF COMMISSION; JURISDICTION OF COURTS.

(a) Whenever the Commission has reason to believe—

(1) that any person, partnership, or corporation is engaged in, or is about to engage in, the dissemination or the causing of the dissemination of any advertisement in violation of section 52 of this title, and

(2) that the enjoining thereof pending the issuance of a complaint by the Commission under section 45 of this title, and until such complaint is dismissed by the Commission or set side by the court on review, or the order of the Commission to cease and desist made thereon has become final within the meaning of section 45 of this title, would be to the interest of the public,

the Commission by any of its attorneys designated by it for such purpose may bring suit in a district court of the United States or in the United States court of any Territory, to enjoin the dissemination or the causing of the dissemination of such advertisement. Upon proper showing a temporary injunction or restraining order shall be granted without bond. Any such suit shall be brought in the district in which such person, partnership, or corporation resides or transacts business.

EXCEPTION OF PERIODICAL PUBLICATIONS.

(b) Whenever it appears to the satisfaction of the court in the case of a newspaper, magazine, periodical, or other publication, published at regular intervals—

(1) that restraining the dissemination of a false advertisement in any particular issue of such publication would delay the delivery of such issue after the regular time therefor, and

(2) that such delay would be due to the method by which the manufacture and distribution of such publication is customarily conducted by the publisher in accordance with sound business practice, and not to any method or device adopted for the evasion of this section or to prevent or delay the issuance of an injunction or restraining order with respect to such false advertisement or any other advertisement,

the court shall exclude such issue from the operation of the restraining order or injunction. Sept. 26, 1914, c. 311, § 13, as added Mar. 21, 1938, c. 49, § 4, 52 Stat. 114.

§ 54. Same; Penalties—Imposition of Penalties.

(a) Any person, partnership, or corporation who violates any provision of section 52(a) of this title shall, if the use of the commodity advertised may be injurious to health because of results from such use under the conditions prescribed in the advertisement thereof, or under such conditions as are customary or usual, or if such violation is with intent to defraud or mislead, be guilty of a misdemeanor, and upon conviction shall be punished by a fine of not more than $5,000 or by imprisonment for not more than six months, or by both such fine and imprisonment; except that if the conviction is for a violation committed after a first conviction of such person, partnership, or corporation, for any violation of such section, punishment shall be by a fine of not more than $10,000 or by imprisonment for not more than one year, or by both such fine and imprisonment: *Provided*, That for the purposes of this section meats and meat food products duly inspected, marked, and labeled in accordance with rules and regulations issued under sections 71-93 of Title [illegible] shall be conclusively presumed not injurious to health at the time the same leave official "establishments."

EXCEPTION OF ADVERTISING MEDIUM OR AGENCY.

(b) No publisher, radio-broadcast licensee, or agency or medium for the dissemination of advertising, except the manufacturer, packer, distributor, or seller of the commodity to which the false advertisement relates, shall be liable under this section by reason of the dissemination by him of any false advertisement, unless he has refused, on the request of the Commission, to furnish the Commission the name and post-office address of the manufacturer, packer, distributor, seller, or advertising agency, residing in the United States, who caused him to disseminate such advertisement. No advertising agency shall be liable under this section by reason of the causing by it of the dissemination of any false advertisement, unless it has refused, on the request of the Commission to furnish the Commission the name and post-office address of the manufacturer, packer, distributor, or seller, residing in the United States, who caused it to cause the dissemination of such advertisement. Sept. 26, 1914, c. 311, § 14, as added Mar. 21, 1938, c. 49, § 4, 52 Stat. 114.

55. ADDITIONAL DEFINITIONS.

For the purposes of sections 52-54 of this title—

FALSE ADVERTISEMENT.

(a) (1) The term "false advertisement" means an advertisement, other than labeling, which is misleading in a material respect, and in determining whether any advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the commodity to which

the advertisement relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual. No advertisement of a drug shall be deemed to be false if it is disseminated only to members of the medical profession, contains no false representation of a material fact, and includes, or is accompanied in each instance by truthful disclosure of, the formula showing quantitatively each ingredient of such drug.

* * * * * *

DRUGS.

(c) The term "drug" means (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clauses (1), (2), or (3); but does not include devices or their components, parts, or accessories.

DEVICE.

(d) The term "device" (except when used in subsection (a) of this section) means instruments, apparatus, and contrivances, including their parts and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

* * * * * *

§56. Proceedings to Enforce Penalty for Violation of Order.

Whenever the Federal Trade Commission has reason to believe that any person, partnership, or corporation is liable to a penalty under section 54 of this title or under subsection (*l*) of section 45 of this title, it shall certify the facts to the Attorney General, whose duty it shall be to cause appropriate proceedings to be brought for the enforcement of the provisions of such section or subsection. Sept. 26, 1914, c. 311, § 16, as added Mar. 21, 1938, c. 49, § 4, 52 Stat. 114.

§57. Separability Clause.

If any provision of sections 41-46 and 47-58 of this title, or the application thereof to any person, partnership, corporation, or circumstance, is held invalid, the remainder of said sections, and the application of such provision to any other person, partnership, corporation, or circumstance, shall not be affected thereby. Sept. 26, 1914, c. 311, § 17, as added Mar. 21, 1938, c. 49, § 4, 52 Stat. 114.

§58. Short Title.

Sections 41-46 and 47-58 of this title may be cited as the "Federal Trade Commission Act." Sept. 26, 1914, c. 311, § 18, as added Mar. 21, 1938, c. 49, § 4, 52 Stat. 114.

FILE COPY

Office-Supreme Court, U.S.
FILED
AUG 31 1959
JAMES R. BROWNING, Clerk

IN THE

Supreme Court of the United States

OCTOBER TERM, 1959.

No. 366.

CARTER PRODUCTS, INC.,

Petitioner,

against

FEDERAL TRADE COMMISSION,

Respondent.

APPENDIX TO PETITION FOR CERTIORARI OF CARTER PRODUCTS, INC. CONTAINING OPINIONS IN THE CASE.

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Opinion of Ninth Circuit Court of Appeals
Filed June 16, 1959.

UNITED STATES COURT OF APPEALS,

FOR THE NINTH CIRCUIT.

CARTER PRODUCTS, INC., Petitioner, *vs.* FEDERAL TRADE COMMISSION, Respondent.	No. 15,373 June 16, 1959

Petition to Review and Set Aside an Order of the Federal Trade Commission.

Before: HEALY, BONE and HAMLEY, Circuit Judges

BONE, Circuit Judge.

The instant case, which has a long history, is before us on a petition by Carter for review of and to set aside a Cease and Desist Order (hereafter "Order") of the Federal Trade Commission (hereafter "Commission") which Order was entered in 1956 at the conclusion of about 149 hearings held before a Hearing Examiner of the Commission. These hearings were held on a complaint of the Commission which charged petitioner Carter Products, Incorporated (hereafter "Carter") with engaging in unfair and deceptive acts and practices in violation of the Federal Trade Commission Act (hereafter the "Act"). The instant litigation was instituted by the Commission's complaint bearing date of May 28, 1943. In the earlier stages of the proceeding, the Commission dismissed its complaint (without prejudice)

as to a co-defendant and the case is now before us with Carter alone seeking a review of the Order.

This litigation was previously before this court and the much narrower issues then presented were disposed of by our opinion and judgment reported in 201 F.2d 446, Carter Products, Inc. *v.* Federal Trade Commission. On certiorari, the Supreme Court vacated this judgment and remanded the cause to this court with directions. 346 U. S. 327. This court thereupon entered judgment as directed by the mandate of the Supreme Court.

Pursuant to our judgment remanding the cause to the Commission for further hearings, these "further hearings" were held before the Hearing Examiner for the Commission who had presided over the first and original set of hearings. At these supplemental hearings conducted in accordance with our said remand order, Doctors Case and Bollman, two of the *three* expert Commission witnesses whose original cross-examination by Carter this court held had been improperly curtailed and restricted, were tendered to Carter for further cross-examination. Because of the intervening death of Dr. Lockwood (one of these three Commission witnesses in the first hearing) this witness could not be tendered for cross-examination and *all* of the testimony and *all* of the exhibits based upon, or connected with, the testimony of Dr. Lockwood in the first set of hearings were stricken by the Hearing Examiner. For this reason, the Lockwood part of the record in the original hearings was not before the Commission for its consideration when it made and entered its formal Decision along with an entirely new set of Findings of Fact and the new Cease and Desist Order which is before us on this review.[1]

[1] The formal "Decision" of the Commission promulgated on October 4, 1956 sets forth therein its FINDINGS AS TO THE FACTS, its Conclusion, and the Cease and Desist Order before us in this review proceeding. In this Decision the Commission points

Opinion of Ninth Circuit Court of Appeals
Filed June 16, 1959.

PRELIMINARY STATEMENT

Because of the great length of the records now before us (which embrace both the original and the supplemental hearings here mentioned)[2] an important aspect of this con-

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out that because of the death of one of the three witnesses whose cross-examination this court had held was improperly curtailed, the entire testimony and all exhibits introduced through that witness (Dr. Lockwood) were, on Carter's motion, stricken by the Hearing Examiner. The Decision also sets forth the formal recitation that "the Commission, having exhaustively considered the entire record, including the evidence adduced after the remand and the briefs and oral arguments of counsel, now finds that this proceeding is in the interest of the public and makes this its modified and supplemental findings as to the facts and its conclusion drawn therefrom, the same to be in lieu of those contained in its decision of March 28, 1951." (The 1951 decision here referred to was the decision which led Carter to file a petition to review and set aside this order. The review in this court eventuated in our opinion in Carter Products, Inc. v. Federal Trade Commission, 201 F.2d 446.)

[2] In the proceeding now before us both parties also cite and rely upon all that appears in the various briefs, records and files lodged in this court in the first review proceeding (201 F.2d 446), save and except all of the testimony of Dr. Lockwood, and all of the exhibits based upon, or connected with his testimony. See our comment on this procedure. The printed transcript filed in this court in that proceeding was in four volumes. This record was also utilized in the supplemental proceedings later held pursuant to the remand directed in our opinion cited supra. The printed transcript filed in this Court and covering the supplemental proceedings appears in ten volumes and, as in the set of printed transcripts in the first review proceedings, appears to contain those parts of the record regarded as pertinent to the inquiry this court must make.

The size of the printed record now before us suggests the conclusion that the further cross-examination of witnesses supporting the Commission's complaint which was directed in our remand, was extensive and searching and fully conformed to our requirement that counsel for Carter be given "broad latitude" in such cross-examination. The testimony of Doctor Case in the supplemental proceedings occupies 164 pages of the printed transcript on this review. The testimony of Doctor Bollman in these supplemental proceedings occupies 300 pages of the printed transcript.

At the conclusion of the first set of hearings counsel for Carter stated to the Examiner that there were then 15,000 pages of testimony in the record (obviously referring to the full reporter's transcript).

Aside from the printed record here noted there was lodged with us in the instant review on the merits an enormous array of documents filed as exhibits in the first hearing in connection with the

troversy should be noted. In the mandate of the Supreme Court on its remand, this court was ordered and directed "to reinstate its prior judgment and order after amending it so that it specifically authorizes the Federal Trade Commission to open this proceeding for further evidence *and a new order consistent with the Court of Appeals opinion herein.*" (Emphasis supplied.)

In the "prior judgment and order" of this court, thus referred to, we set aside the order of the Commission, and specifically indicated therein our reasons for this action. We held that Carter had been denied a fair hearing *because* the Hearing Examiner had unduly and prejudicially restricted Carter's right to cross-examine the three above mentioned expert witnesses who had appeared in support of the allegations of the Commission's complaint; that the error of the examiner was his failure to permit a "broad latitude" in the cross-examination of these three witnesses.[3]

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testimony of witnesses in proceedings before the Hearing Examiner. Commission's brief points out that in this first hearing (ending in 1943) 2269 exhibits were introduced in evidence.

The exhibits admitted in evidence in the hearings also include many copies or photostats of announcer's scripts used in radio "broadcasts" in which broadcasts Carter made many elaborate claims concerning the therapeutic action and value of its pills. Along with these radio exhibits were many photostatic copies of advertisements which Carter had caused to be published in various publications in the United States and in which advertising matter the same claims were made concerning the therapeutic action and quality of its pills. In the aggregate, these radio broadcasts and the newspaper and or magazine ads contained an array of the advertising claims of Carter which the Commission's complaint repeats, and therein asserts were false and misleading, and which the 1956 findings of the Commission as to the facts also assert were false and misleading in many material respects.

[3] In its Petition to this court to review and set aside the final Cease and Desist Order of the Commission which was issued on October 4, 1956, Carter avers, inter alia, that this court had held that Doctors Case, Bollman and Lockwood were "key witnesses of the Commission"; that it was the "unjustifiable restrictions" on the cross-examination of these "key witnesses" that deprived Carter of a fair hearing; that on February 9, 1955 the Hearing Examiner issued written rulings denying certain motions of Carter including its motion to strike the testimony of "key witnesses" Doctors Case

So that no doubt might remain concerning the exact reason for our action, we there carefully identified the particular rulings of the Hearing Examiner which we assailed and which we concluded had caused Carter to be denied a fair hearing.[4]

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and Bollman, along with Carter's written "offers of proof and additional evidence" all dated May 26, 1954; that the Hearing Examiner did strike the testimony of Dr. Lockwood; that on March 3, 1955, the Hearing Examiner entered his order closing the case.

Carter's said petition for review further avers that it moved the Commission to disqualify the Hearing Examiner and terminate these proceedings; that on March 3, 1955, and before the Commission could decide the motion to disqualify the Hearing Examiner, that officer filed his Supplemental Report with respect to the proceedings on remand, and therein recommended the issuance by the Commission of the same form of Cease and Desist Order as previously entered by the Commission in 1951; that on September 20, 1955, the Commission denied Carter's motion to disqualify the Examiner, strike his Supplemental Report, and terminate these proceedings; that on appeal to the Commission Carter renewed its said motions and filed its proposed findings and conclusions of law; that thereafter and on October 4, 1956, the Commission issued its Cease and Desist Order in substantially identical form with its previous Cease and Desist Order dated March 28, 1951. (See footnote 1, supra.)

Carter prayed that this court strike the Supplemental Report of the Hearing Examiner, terminate the instant proceeding, and reverse and set aside the Cease and Desist Order now before us.

[4] It was this particular curtailment of cross-examination in the original hearings which caused this court to set aside the Commission's order and led this court to declare in its opinion and decision, 201 F.2d at page 448, that "Questions pertaining to the sufficiency of the evidence or to the merits are not presented by the petition. What is claimed, principally, is that a fair hearing was denied petitioner in that the trial examiner unduly and prejudicially restricted its right of cross-examining certain of the Commission's expert witnesses upon whose testimony, in large measure, the [March 28, 1951] findings and order were based. The witnesses in question were Doctors Carlson, Bollman, Lockwood, and Case. We are of the opinion that petitioner's claim is well grounded in respect of the three experts last named, but not in respect of the witness Carlson."

Relative to this same "principal claim" of Carter, we ended our opinion with the further comment (at p. 454) "It is argued that there was ample evidence from other quarters to sustain the findings and order of the Commission, hence the rulings, even if wrong, were not prejudicial. We are of the opinion, however, that the cumulative effect of these unjustifiable restrictions on the cross-examination of key witnesses for the Commission was to deprive petitioner of a fair hearing. Such being the case the court is not disposed to speculate

It is also our firm conclusion that if the *new order* of the Commission so authorized in our order of remand was to be truly "consistent with" our opinion (as directed by the Supreme Court) this *new order* would have to be bottomed on the evidence and testimony received in the original hearings (except where appropriately stricken as in the case of Dr. Lockwood) *plus* the "further evidence" adduced in the renewed and additional cross-examination of two of the Commission's above noted expert witnesses in the supplemental hearings which followed the remand. If it be the view of Carter that our order of remand required a proceeding *de novo*, or was properly to be construed (in light of the direction from the Supreme Court) as an invitation or suggestion that the proceedings might (also) be opened for the purpose of receiving additional testimony

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as to what would have been the outcome had a fair and impartial hearing been accorded."

In discussing at one point in our said opinion the latitude to be allowed in the cross-examination of expert witnesses, we referred to the fact that the Examiner imposed upon Carter the condition that it make Dr. Lockwood its own witness and we characterized this action (p. 452) as "flagrant error." As noted supra in this opinion, the death of Dr. Lockwood caused the Hearing Examiner to later strike from the records in this proceeding all of the testimony and all of the exhibits based upon, or connected with, the testimony of Dr. Lockwood in the first set of hearings. As a consequence of this action, the record shows that the new set of Findings of Fact and the new Cease and Desist Order now before us and which were entered by the Commission under date of October 4, 1956, do not rest in any degree upon the Lockwood testimony and the exhibits based upon or connected therewith, and in our view the "flagrant error" we mentioned has ceased to be a factor in this proceeding.

Because a question arose concerning the probative value and admissibility of testimony relating to experiments on dogs and human patients, this court also took occasion to comment upon this phase of the proceedings before the Hearing Examiner. In footnote 1 of our previous decision, supra, (p. 448) we said: "Petitioner also urges that fatal error was committed in admitting evidence pertaining to certain experiments on dogs and human patients. In our opinion the objection to these experiments, several of which will be mentioned hereafter, goes to their weight only, not to their admissibility."

On this review we find no reason to part company with the views we previously expressed in this footnote.

from witnesses other than the two expert witnesses we have mentioned (Case and Bollman) we must disagree with Carter since our conclusion is to the contrary.

After Case and Bollman were further cross-examined at length in the following supplemental hearings above referred to, and on October 4, 1956, the Commission made and entered an entirely new and second set of Findings of Fact, a Conclusion of Law, its formal Decision (see footnote 1) and the Cease and Desist Order[5] which is here

[5] The formal Decision of the Commission embodies its final Cease and Desist Order, its Conclusion of Law, and its "Findings as to the Facts." The Conclusion of Law and the Cease and Desist Order now before us read as follows:

CONCLUSION

"The acts and practices of the respondent, as herein found, are all to the prejudice and injury of the public and constitute unfair and deceptive acts and practices in commerce within the intent and meaning of the Federal Trade Commission Act."

FINAL ORDER

"It Is Ordered that the respondent, Carter Products, Inc., a corporation, and its officers, agents, representatives and employees, directly or through any corporate or other device, in connection with the offering for sale, sale, or distribution of the product now designated 'Carter's Little Liver Pills,' or any other product of substantially similar composition or possessing substantially similar properties under whatever name sold, do forthwith cease and desist from:

"(1) Disseminating or causing to be disseminated any advertisement by means of the United States mails or by any means in commerce, as 'commerce' is defined in the Federal Trade Commission Act, which advertisement represents directly or by implication—

"(a) That said preparation represents a fundamental principle of nature in self-treatment;

"(b) That said preparation will bring on or restore regularity of bowel movement, or is a cure, remedy or competent or effective treatment for constipation, or has any beneficial value in the treatment of any of the symptoms thereof in excess of the temporary relief afforded by its laxative action;

"(c) That said preparation does not contain strong medicines;

"(d) That said preparation is unqualifiedly safe;

"(e) That said preparation is an effective treatment for sluggish liver function or that it will have any therapeutic action on any condition, disease or disorder of the liver;

involved. A formal Opinion of the Commission was also filed on October 4, 1956. For reference to date and place of publication of an official copy of the here noted Commission's Cease and Desist Order, see last paragraph of footnote 5.

"(f) That said preparation will make bile flow freely, increase or beneficially influence the formation, secretion or flow of bile, or prevent or overcome discomforts caused by over-indulgence in food or other pleasures;

"(g) That said preparation will provide two-way relief or that it possesses therapeutic properties in addition to those afforded by laxative action;

"(h) That said preparation will cause the proper flow of, or beneficially affect, the gastric juices or digestive juices, or lessen food decay;

"(i) That said preparation is based on the fundamental principle of the operation of the digestive system;

"(j) That said preparation will help food digestion, or regulate digestion or the digestive system;

"(k) That said preparation will have any influence in inducing a state of 'bounce,' vigor or well-being except in those instances in which a lack thereof is due solely to constipation;

"(l) That constipation poisons the body;

"(m) That said preparation has any value in the treatment of headache, ugly complexion, bad breath, coated tongue or a bad taste in the mouth, or for those conditions in which an individual feels 'Down-and-out,' 'blue,' 'down-in-the-dumps,' 'worn out,' 'sunk,' 'logy,' 'depressed,' 'sluggish,' 'all-in,' 'listless,' 'mean,' 'low,' 'cross,' 'tired,' 'stuffy,' 'heavy,' 'miserable,' 'sour,' 'grouchy,' 'irritable,' 'cranky,' 'peevish,' 'fagged out,' 'dull,' 'sullen,' 'what's-the-use,' 'bogged down,' 'grumpy,' 'run-down,' or 'gloomy,' in excess of such temporary relief therefrom as may be afforded by an evacuation of the bowels in those cases in which such symptoms or conditions are associated with and caused by constipation;

"(n) That said preparation is a competent or effective treatment for indigestion or retarded digestion;

"(o) That said preparation is a competent or effective treatment for biliousness.

"(2) Disseminating or causing to be disseminated any advertisement by means of the United States mails or by any means in commerce, as 'commerce' is defined in the Federal Trade Commission Act, in which the word 'Liver' is used in the trade name for the respondent's preparation.

"(3) Disseminating or causing to be disseminated any advertisement by any means for the purpose of inducing or which is likely

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Applicable provisions of the Act with which we are here concerned are:

> "Sec. 5(a)(1). [Section 45 (a)(1) of Title 15, U.S.C.A.] * * * unfair or deceptive acts or practices in commerce, are declared unlawful.
>
> "Sec. 5(a)(6). [Section 45 (a)(6) of Title 15, U.S.C.A.] The Commission is empowered and directed to prevent persons, partnerships, or corporations * * * from using * * * unfair or deceptive acts or practices in commerce."

Pursuant to the order authorizing the Commission to open the proceedings for the further evidence mentioned and for entry of a new order consistent with the opinion of this court, the Commission did, by order, reopen the proceeding and refer it to the Hearing Examiner "for such further proceedings as may be necessary to correct the errors in the original hearings as specified by the Court of Appeals." The examiner was directed to file "a report upon the additional evidence and state the changes, if any, he wishes to make in his original recommended decision as a result of such additional evidence."

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to induce, directly or indirectly, the purchase of said product in commerce, as 'commerce' is defined in the Federal Trade Commission Act, which advertisement contains any representation prohibited in paragraphs (1) and (2) hereof.

"It Is Further Ordered that the charges of the complaint as they relate to the respondent Street & Finney, a corporation, be, and the same hereby are, dismissed without prejudice to the right of the Commission to take such further action as future conditions may warrant.

"It Is Further Ordered that the respondent, Carter Products, Inc., shall, within sixty (60) days after service upon it of this order, file with the Commission a report in writing setting forth in detail the manner and form in which it has complied with this order.

"By the Commission, Commissioner Mason not participating.

"Issued: October 4, 1956."

An official copy of the above Cease and Desist Order was published in the October 23, 1956 issue of the Federal Register, Volume 21, Number 206.

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After an order of the examiner was later made closing the record and denying Carter's motion and offers of certain proof, Carter (on April 18, 1955) filed a motion to disqualify the Hearing Examiner from taking any further action in this proceeding, and for an order wholly terminating these proceedings because of bias of the examiner. Subsequently, the examiner filed his supplemental report and his recommendation. Later on, and in an opinion carefully analyzing the issues tendered by the said motion, the Commission denied Carter's motion to disqualify the examiner and to terminate the proceedings.

We are of the opinion that the question whether the Hearing Examiner should have been disqualified (for the reason urged by Carter) and in addition the hearings terminated, presented issues the disposition of which rested in the sound discretion of the Commission. From the record as a whole we cannot conclude as a matter of law that the Commission abused its discretion when it denied Carter's said motion for the relief here mentioned.

As the Commission emphasizes in its brief, the issues in this case were adjudicated by the Commission under a procedure in which the examiner files only a "recommended decision," i.e., a "report upon the evidence" as provided by a rule of the Commission in effect when the proceedings were instituted. Therefore, the examiner in the instant matter did not make an "initial decision," as is required under the present procedure. It should be noted that in this proceeding the Commission made its own formal findings as to the facts, its own conclusion and issued its own order to cease and desist. While the Commission's "rule" here referred to required the trial examiner to make a "report" upon the evidence to the Commission, this controlling rule also provided that such a report was advisory only and not binding upon the Commission.

For many years Carter has engaged in the sale and distribution in interstate commerce of its laxative pills

sold under the Trade Mark or trade name of "Carter's Little Liver Pills." These pills are admittedly sold as a laxative and admittedly contain only two active drugs—aloes and podophyllum. On this review the Commission takes the position that the evidence adduced in support of the allegations of the complaint clearly establishes that these two drugs are recognized as "irritative laxatives"; that this evidence shows that Carter repeatedly made, and is making, false representations in its general advertising in commerce that use of its medicinal preparation will stimulate the production and flow of liver bile thereby rapidly improving the health of users; that Carter also falsely claims in this widely disseminated advertising that use of its pills provides an effective treatment for a vast array of common human ailments, including disorders and diseases of the liver, and that many of these claims constitute false representations in advertising; that this sort of conduct constitutes unfair and deceptive acts and practices in interstate commerce within the meaning of Section 5 of the Federal Trade Commission Act, supra. Highlighting the position of Commission counsel is their assertion that the actual area of factual *conflict* in this proceeding relates simply and solely to what influence, if any, Carter's laxative pill will have on the production and flow of liver bile. Our examination of the medical evidence and testimony in the record leads us to conclude that this position of counsel finds strong support in the records. (See footnotes 7 and 8, infra.)

THE COMPLAINT.

The Commission's complaint directed against the advertising claims of Carter covers sixteen pages of the printed transcript and sets forth a long array of charges. In general, it avers that in furtherance of the sale and distribution of its medicinal preparation known as "Carter's Little

Liver Pills," Carter has disseminated and now is disseminating many false and misleading advertisements to the general public concerning this preparation, and also making disparaging statements about the drug calomel and other laxative preparations, this by use of the United States mails and by various means in commerce as defined by the Act. The complaint charges that the dissemination of this false advertising by Carter was for the purpose of inducing, and was likely to induce, directly or indirectly, the purchase of Carter's preparation "Carter's Little Liver Pills" in commerce, as "commerce" is defined in the Act.

The length of the complaint and the answer of Carter requires that we summarize these pleadings. In our summary of the complaint we shall indicate the general character of the charges appearing in some of the paragraphs wherein certain advertising claims of Carter are carefully specified in detail, but we do not undertake to list all of the advertising claims noted in the complaint. In the hearings, the proof that a great array of these advertising claims had been made by Carter by publication in newspaper ads and in "commercial announcements" in radio broadcasts, was presented by introducing (apparently without objection) copies of these ads and the radio announcers' scripts. To list at this point all of the claims thus shown concerning the alleged merits of Carter's preparation would expand this opinion beyond any reasonable length. The Commission's complaint however sets them out in elaborate detail.

As we shall later note, the Cease and Desist Order of the Commission now before us (footnote 5, supra) does not enjoin the use of *all* of the many advertising claims of Carter described in the complaint; it specifically enjoins Carter from use of certain advertising claims which are carefully described in the Order.

The complaint (paragraph 6), inter alia, charges in lengthy detail that by and through the use of words, phrases, statements and representations appearing in the advertis-

ing material disseminated and caused to be disseminated by Carter (as above noted) which purport to be descriptive of the preparation "Carter's Little Liver Pills," and descriptive of their therapeutic action, and the result and value of the action of this preparation, Carter therein represents directly and by implication, among other things, that its preparation:—represents a fundamental principle of nature in self-treatment; is a competent and effective treatment for a condition designated as a "sluggish liver"; will "wake up the flow of [liver] bile"; is "effective in making bile flow freely by getting the liver back to normal and back to producing"; will cause the proper flow of gastric juices, natural vital digestive juices and vital alkaline juices; is based on the fundamental principle of the operation of the digestive system, and will "help food digestion," "lessen food decay," regulate digestion and the digestive system; will bring on, help and restore regularity and is a cure and remedy and constitutes a competent and effective treatment for constipation; will clear away the "dark clouds of listlessness and despondency" and "give one's personality a chance"; will "keep up one's pep and vigor"; will "make one feel good and up-to par again" and "keep one smiling and happy"; will "eliminate those uncomfortable feelings" that cause a bad disposition and will keep good dispositions "cheerful, happy and a regular thing"; and will help in more ways than one to make one feel better again fast and differently and will provide *two-way relief*.[6]

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[6] In many of Carter's representations appearing in its advertising material placed in evidence, there appears the claim that Carter's preparation will give the user "two-way relief." This "two-way relief" was generally described by Carter as relief from "irregularity" without disturbing digestion, and also a stimulation of the liver which would cause a flow of two pints of bile per day. Such advertisements frequently emphasized that Carter's pills were a "laxative plus" because they provided this sort of "twoway relief." The Commission's Cease and Desist Order enjoins Carter from further use of the term "two-way relief" in its advertising. See note 5, supra.

Many of the exhibits in evidence were extracts from radio scripts used in national promotion of sales of Carter's pills. These radio

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The complaint further charges (in paragraph 6) inter alia, that in its said advertising Carter has represented directly and by implication that its preparation "follows nature's own order for regularity and so regulates the

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advertisements lauded the unusual therapeutic virtues of Carter's pills, emphasizing that they were "Laxative Plus" which provided a unique form of gentle "two-way relief" not to be found in any other simple laxative, including calomel. Just below we quote the language used by Carter in some of the many radio advertising scripts here mentioned.

"They [Carter's Little Liver Pills] provide two-way relief—relief you cannot expect from a simple laxative alone. First, they help wake up the flow of bile—a vital digestive juice. And they usually start to do this within 30 minutes after taking. Second, they help restore regularity. In days gone by, folks took calomel to get results like this. But today you get gentle relief from Carter's without the ordeal of calomel."

"Scientific facts show it takes a two-way treatment to get the vital digestive juice [bile] flowing quickly—and to relieve sluggishness without disturbing digestion. Now—this type of two-way treatment follows Nature's own order for regularity.—Remember—many ordinary simple laxatives *DON'T*—but Carter's Little Liver Pills *DO* give this two-way treatment you want. Only genuine Carter's have this proven formula."

"Medical knowledge proves that Nature must produce about two full pints of the vital digestive juice [bile] your liver makes each day. Otherwise, your food may not digest properly—and leave you feeling dull, headachy, sluggish. Scientific facts show it takes a two-way treatment to get the vital digestive juice flowing quickly—and to relieve sluggishness without disturbing digestion. Now—this type of two-way treatment follows Nature's own order for regularity."

"First—Carter's starts your liver bile flowing quickly. Second—Carter's gently help you to that glorious feeling that goes with regularity."

"One of the reasons for irregularity is that sometimes the alkaline digestive juices don't flow fast enough to help digest the food you eat. Another reason is that sometimes the peristaltic waves slow down. Many laxatives have no effect on the Alkaline Juices I'm talking about. Many of 'em only stimulate the peristaltic waves. But there's one laxative that may increase the flow of these vital Alkaline Juices. That's why we call it a Laxative Plus. By this time, I'm sure most of you know that I'm talking about Carter's Little Liver Pills."

"When two pints of that juice [bile] flow through our lower food canal every day, irregularity, gas, bloating, fatty indigestion below the belt and bilious grouch may go away. Then many of us may feel full of joy like a barefoot boy. Carter's Little Liver Pills are made of two simple vegetable medicines. No calomel in them."

digestive process that, if it is taken as directed before retiring at night, one will awaken the following morning feeling the way one wants to feel, but he will also discover that such use (as directed) of Carter's preparation will bring about (as specifically enumerated in the complaint) some 44 (additional) physical reactions and manifestations in the user's body all indicating the restoration of pep, physical vigor and a feeling of well-being. It is further charged in paragraph 6 that Carter's advertising has represented that use of its preparation will so influence the production or flow of liver bile that one can overeat and overindulge in "good times", without the usual ordinary discomfiture resulting therefrom, and that Carter's product will overcome the effects that ordinarily follow such indiscretions, this by reason of its stimulating influence on the production or flow of liver bile.

The complaint also charges in paragraph 6, inter alia, that in its said advertising Carter has represented that its preparation "does not contain any strong medicine" and is "safe to use"; that "it is not an ordinary laxative but possesses therapeutic properties over and above and in addition to its laxative action." The complaint, in paragraph 7, alleges, inter alia, that Carter's advertising material has (also) disseminated and caused to be disseminated, as aforesaid, material which purports to describe approximately 66 abnormal physical conditions and distressing mental attitudes (specifically noted in the complaint) and as to these it is alleged by the Commission that Carter advertised that "if any individual feels" *any* of these "conditions," i. e., suffers from *any* of them, "then such person is exhibiting symptoms, manifestations or conditions indicating irregularity of bowel movement or constipation; that irregularity of bowel movement or constipation is the cause of such symptoms, manifestations or conditions"; that "the preparation 'Carter's Little Liver Pills' is a competent and effective treatment for such symptoms,

manifestations and conditions." Also, that Carter further represented in its advertising material, among other things, in the manner, means and method aforesaid, that constipation poisons one's body.

Paragraph 8 of the complaint charges that advertising material has been disseminated in commerce by Carter in which material it purports to describe the "therapeutic action" of its preparation, and the result and greater value of such action in an invidious comparison with the value of calomel and other laxative preparations or compounds sold on the market. In this connection, it is charged that Carter's advertising material has represented directly and by implication, among other things, that calomel, "is a harsh, drastic, dangerous laxative, the use of which is an ordeal and puts one through the wringer"; that "other ordinary laxative preparations or compounds sold on the market do not possess the same desirable therapeutic action nor will the use thereof be as effective, or produce as beneficial results," as Carter's product; and that this product "is superior to such laxative preparations or compounds."

Paragraph 9 of the complaint also charges, inter alia, that all of Carter's advertising claims (noted above) are "grossly exaggerated, false and misleading," and it further avers that Carter's Little Liver Pills do not represent a fundamental principle of nature in self-treatment; that they are not effective in making liver bile flow freely; that they will not get the liver back to normal or back to "producing" (bile), nor will they cause the proper flow of the gastric juices, natural vital digestive juices or vital alkaline juices; that Carter's pills are not based on the fundamental principle of the operation of the digestive system, and will not help "food digestion" nor lessen "food decay," nor will they regulate digestion or the digestive system; that to the contrary, Carter's preparation "is likely to interfere with the digestive process," and will not bring on, help or restore "regularity"; that it does not consti-

tute a competent or effective treatment for constipation, and it will not produce in the users of the preparation the 36 different physical indications of abounding health and vitality (enumerated in this paragraph) and which Carter had advertised will result from the use of its preparation. Paragraph 9 further charges that Carter's preparation will not influence the production or flow of liver bile so as to enable one to overeat or overindulge in "good times" without experiencing the usual discomforts resulting therefrom; that it will not (if taken as directed by Carter) cause one to awaken feeling better (in the 36 ways specified in this paragraph) as advertised by Carter; that Carter's preparation does "contain strong medicines," and that "it is not safe to use under all circumstances"—that it is "an ordinary laxative or cathartic and possesses no therapeutic properties over, above, or in addition to, its laxative action."

Paragraph 10 of the complaint refers to and describes approximately 59 distressing physical conditions and unhappy mental attitudes mentioned in Carter's advertising. (See reference in paragraph 7 to these and/or similar physical troubles which Carter's advertising indicated would be eliminated by use of Carter's preparation.) Paragraph 10 charges that the existence of one or more of such 59 symptoms, manifestations or conditions does not indicate that the individual is suffering from irregularity of bowel movement or from constipation; that Carter's preparation is not a competent or effective treatment for such symptoms, manifestations or conditions; that when such symptoms or manifestations are caused by, or associated with, irregularity of bowel movement, then Carter's preparation "will have no greater therapeutic value in the treatment thereof than the temporary relief afforded by an evacuation of the bowels." It is further avered in this paragraph that Carter's pills "will have no therapeutic action, effect or influence on the secretion and flow of bile

and will therefore have no therapeutic value, whatever, in the treatment of any symptom, manifestation or condition, under whatever name or names designated, caused by or due to disorders in the secretion and flow of bile—that according to the consensus of opinion of recognized scientific and medical authority, constipation does not poison one's body."

Paragraph 11 of the complaint alleges that calomel used with proper caution and given in proper doses for, and taken in a proper manner to act as a laxative, is not dangerous; and it is no more drastic in its action, nor is the taking thereof any more of "an ordeal," nor does it "put one through the wringer" to any greater degree than Carter's preparation which is an ordinary laxative or cathartic possessing no other therapeutic property; that the action of Carter's preparation is no different from, nor will the results obtained from its use be any more effective or beneficial than, that obtained from the use of many other ordinary laxative preparations and compounds containing vegetable laxative or cathartic drugs sold on the market; that Carter's preparation is not superior to such other laxative preparations or compounds.

The complaint (paragraph 12) also generally charges, inter alia, that Carter engaged in further false and misleading representations in reference to its preparation through and by the use of the word "Liver" in the name "Carter's Little Liver Pills" used in its advertising material to identify and describe the medicinal preparation it sold and distributed; that Carter there represented, directly and by implication, that its preparation is for use in the treatment of conditions, disorders and diseases of the liver and that said preparation will have some therapeutic action, effect and influence on the liver. The complaint further alleges that Carter's pills contain no ingredient or ingredients, recognized by competent medical or scientific authority, either alone or in any combination of the one with the

other, as having any therapeutic value in the treatment of any condition, disorder or disease of the liver, or that the ingredients in the said pills, alone or in any combination of the one with the other, will have any action, effect or influence, corrective or otherwise on the liver.

The complaint (paragraph 13) further avers that Carter's advertisements were false inasmuch as they represent its pills as a competent, effective, safe treatment for common and recurrent pains and fail to reveal facts material in the light of such representations or material in respect to the consequences that may result from the use of the preparation under conditions described in the said advertisements or under such conditions as are customary or usual; that Carter's preparation is an irritant laxative or cathartic which is potentially dangerous if taken by persons suffering from abdominal pains, nausea, vomiting or other symptoms of appendicitis.

The complaint avers generally in paragraph 14 that Carter's advertising material does not accurately disclose or describe its preparation or the true results to be obtained from its use, all of which misleads the public into the erroneous and mistaken belief (1) that the use of Carter's preparation will have the effect and accomplish the results claimed for it by Carter, as set forth in paragraphs 6 and 7 of the complaint, (2) that its preparation is superior to calomel and superior to other ordinary laxatives sold on the market, (3) that it will have some therapeutic action, effect and influence on the liver, and or that it is for use in the treatment of conditions, disorders and diseases of the liver, (4) that it is safe to take. The complaint further avers in this paragraph that Carter's advertising material "has had and now has the tendency and capacity to, and might easily, induce a substantial portion of the purchasing public, because of such erroneous and mistaken beliefs, to purchase" Carter's preparation.

And see our later reference to dismissal of two charges set forth in the Commission's complaint. Commission's finding No. 19 orders dismissal of these two charges.

The complaint finally avers that the acts and practices of Carter (in its noted advertising) are all to the prejudice and injury of the public and constitute unfair and deceptive acts and practices in commerce within the intent and meaning of the Act.

Carter's Answer

Carter filed an answer in July, 1943 in which it admitted its identity, the sale of its product and the dissemination of advertisements containing statements and representations concerning its laxative pill, a list of which is set forth in the Commission's Complaint.

While admitting in its answer the use of certain of the representations appearing in its advertising material (as shown by the evidence) the answer averred that as to such representations the Commission's complaint was so framed as to attribute to many of Carter's therapeutic claims *a meaning* which Carter did not intend in making the claims. It further averred therein that some of the advertising claims noted in the complaint had been abandoned for a long time; that some of these advertising claims were regarded by Carter "as permissible trade puffery or permissible sales talk," and others as being supported by competent evidence. The answer charged that paragraph 6 of the complaint "contains facts, innuendoes and inferences built upon inferences."

The answer admitted that many of the words and phrases set forth in paragraph 7 of the complaint had been used to advertise Carter's pills, and denied that it had claimed that constipation poisons one's body. It averred that the drugs in its pills "act upon the liver to stimulate the flow of bile," and denied that it had ever repre-

sented its product "for treatment of disorders of the liver generally."

Carter finally averred that its advertising of its product "truthfully describe its properties"; that "the mere fact that one may be mistaken in some respects with regard to the physiological action of Carter's Little Liver Pills does not establish as a matter of law that the seller is guilty of unfair or deceptive acts or practices or that its advertising is misleading in a material respect."

Without going further into detail, it is our view that the averments in Carter's answer put in issue all of the material averments in the Commission's complaint.

The pleadings as thus framed remained unchanged through all stages of the instant litigation. After issue was thus joined, *the first series* of extended hearings were held before an examiner, beginning in November 1943 and ending in November 1945. Upon completion of these first hearings, the examiner made his formal "Report" to the Commission on July 22, 1946. In an earlier part of this opinion we called attention to the procedures which were standard practice in proceedings before the Commission at the time this controversy began. The proceedings were therefore *continued under this practice* after this court had remanded the cause for such further proceedings.

This (1946) "Report" of the Hearing Examiner occupies (with its two addendums) approximately 267 pages of the printed transcript. It sets forth a carefully detailed analysis of the testimony and evidence submitted in the first series of hearings. It includes his conclusions of fact and law and a recommendation that the Commission issue a Cease and Desist Order prohibiting Carter (and its then co-respondent Street & Finney, a New York Corporation which had been handling Carter's advertising) from continuing the acts and practices which the examiner found to be in violation of the Act.

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In the Commission's *first* disposition of this case by its Cease and Desist Order issued in 1951 the Commission followed the then applicable (and above referred to) procedure in which the Hearing Examiner filed only a "recommended decision," this being done pursuant to a rule of the Commission in effect when the proceedings were originally instituted in 1943. In the second series of hearings held after and pursuant to our order of remand under the order of the Supreme Court, the Hearing Examiner and the Commission continued to proceed under the above noted Commission's rules effective in 1943, since the remand merely continued proceedings which had been interrupted by the first review proceeding in this court. In disposing of the issues arising out of the second series of hearings following the remand, the Hearing Examiner continued to follow the said 1943 Commission rules and did not make an "initial decision" *as is required by procedures now followed.* In the (1956) record before us on this review the Commission ultimately made its own findings as to the facts, its own Conclusion of Law, and formulated its own Order to Cease and Desist. Thus, its ultimate decision now before us on review was not one fashioned by the Hearing Examiner but was that of the Commission itself. This decision was rested upon the entire record in *all* of the various proceedings had in this controversy save and except that part relating to the testimony of Dr. Lockwood.

At the conclusion of all testimony taken *after* our above noted order of remand, and under date of March 31, 1955, the Hearing Examiner filed his Supplemental Report upon the additional evidence received, along with his recommendations to the Commission. In this document the Hearing Examiner, among other matters, described certain past proceedings had in this litigation and this recital was followed by his description of the additional evidence presented by and through the testimony of Doctors Case and Bollman (see footnote 2) and comments on contentions raised by counsel for Carter.

This (1955) Supplemental Report ends with the "Conclusion" of the Hearing Examiner wherein he stated that he finds no reason to alter, change, amend, add to, or detract from, his original Findings as to the Facts, Conclusion of Law and Recommendation for Appropriate Action, all as set forth in his above noted original Report to the Commission of July 22, 1946. The Hearing Officer also stated therein that "the deletion of the testimony of (the deceased) Dr. Lockwood in nowise detracts from the validity of this decision to adhere to the original recommendations, nor does the disregard of Dr. Bollman's testimony in support of [a certain Commission exhibit] alter such determination * * *." The "Conclusion" ends with the Examiner's general comment that "because of the additional testimony [of Doctors Case and Bollman] and the opportunity to again study, review and appraise the entire record after a lapse of nine years [he] is firm in his conviction that the record fully justifies all findings, conclusions and recommendations originally made [in 1946] and hereby renews his recommendations that an appropriate order be issued consonant therewith."

THE "DECISION" OF THE COMMISSION

Prior to the making and entry of the final and formal "Decision" of the Commission before us in the instant proceeding (which document bears date of October 4, 1956) counsel for both sides filed briefs with the Commission in which they tendered comprehensive arguments on the merits of the entire case.

Following the filing of these briefs counsel presented oral arguments before the Commission on June 18, 1956 in support of the contentions set forth in their respective briefs. Thereafter, the "Decision" above mentioned was entered. Among other matters discussed in this Decision, the Commission made a preliminary comment on certain

antecedent procedures in this prolonged controversy including therein a reference to the denial by the Commission of a motion by Carter (referred to supra in this opinion) to disqualify the Hearing Examiner for alleged bias and prejudice. The Decision also refers to the oral arguments of counsel presented before the Commission on June 18, 1956.

A formal "Opinion" of the Commission was also entered on October 4, 1956. In this Opinion the Commission also discusses the (April 18, 1955) motion of Carter to disqualify the Hearing Examiner who had previously taken all of the testimony in this proceeding. In this motion Carter prayed for an order disqualifying the said Hearing Officer and sought *a hearing de novo* before another hearing officer, or in the alternative, an order dismissing the entire proceeding for failure of proof. The Commission's Opinion rejected Carter's above noted motion and, inter alia, recites that its "Decision" represents "the result of its own exhaustive examination of the record." Earlier in this opinion we held that the Commission did not abuse its discretion in rejecting Carter's said motion.

The "Decision" of the Commission contains the formal findings of ultimate probative facts developed in the evidence and testimony in this proceeding and occupies approximately 50 pages of the printed transcript in cause No. 15373. Of necessity we must confine ourselves to a summary of the findings which deal immediately and directly with what we regard as the most pertinent fact issues in this case. Preliminarily, the Commission recites that having "exhaustively considered the entire record, including the evidence adduced after the remand and [after] the briefs and oral arguments of counsel," it "makes this its modified and supplemental findings as to the facts and its conclusion drawn therefrom, the same to be in lieu of those contained in its decision of March 28, 1951." (See footnote 1.)

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After other preliminary findings in the Decision as to Carter's status as a corporate entity and as a litigant, the findings refer to the sale practices of Carter which bring its Commission-condemned advertising operations into the current of interstate commerce and portray its use of this advertising material as one designed for the purpose of inducing, directly or indirectly, the purchase of its medicinal preparation in such commerce. The Decision then sets forth various findings of fact as to the precise nature and character of the advertising representations disseminated by Carter in commerce all as more completely charged in the Commission's complaint and as shown in detail in the exhibits in evidence.

Both the Decision and the Opinion of the Commission contain pointed references to the briefs of counsel and their oral argument on the merits at the conclusion of all proceedings before the Commission. In the margin we comment on this phase of the proceedings.[7]

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[7] The final oral arguments before the Commission were presented on June 18, 1956. They appear in Volume 8 of the Printed transcript in proceeding No. 15373 in this court at pp. 3472 to 3530, inclusive. The findings of fact set forth in the final Decision of the Commission and in its formal Opinion contain several comments upon these oral arguments but their length forbids inclusion in this opinion. However, a brief reference to the arguments before the Commission, and the very significant contentions therein voiced, will be helpful in arriving at a definite understanding of just what opposing counsel regarded as the exact issue or issues which had to be finally decided by the Commission. The great value of these arguments lies in their refreshing candor and frankness, and the purpose of counsel was to narrow the issues facing the Commission to the limited area of controversy there clearly portrayed by counsel. And additionally, it is to be noted that subsequently (and in four of its later noted findings) the Commission on its own motion also materially narrowed the material fact issues which this court is called upon to resolve in its review of the record.

In his oral argument, counsel for Carter stated to the Commission: "I have argued in my brief that one of the tasks this Commission has before it is to review the entire record and make new findings, because the old ones [set out at pages 305 to 333 of the printed transcript in cause No. 12940 in this court] are out the

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THE COMMISSION'S FINDINGS OF FACT

The ultimate findings of fact entered by the Commission appear in and as part of its Decision dated October 4,

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window. You can't make findings on the basis of an incomplete record."

(We have noted in an earlier part of this opinion, that following the second set of hearings the Commission did make and enter an entirely new, second, final and controlling set of Findings of Fact, a Conclusion of Law based thereon, and a formal Cease and Desist Order, these being the instruments made and filed on October 4, 1956.) (See footnotes 1 and 2, supra.)

Concerning just what material issues had finally emerged as the end result of the two series of hearings before the Hearing Examiner during which proceedings (according to Carter's counsel) "thousands of exhibits" had been introduced in evidence, Carter's counsel frankly stated to the Commission: "I think over the course of the years, it has pretty much simmered down to two issues, one, whether or not the ingredients of Carter's Pills—namely aloes and podophyllin will stimulate the flow of bile from the liver. The other is a corollary that flows from that, is the company entitled to use the word 'liver' in the title of its name, Carter's Little Liver Pills, as it has done now, I think, for about 75 years?" This statement is certainly blunt enough to remove any and all doubt as to what Carter regarded as the controlling issues which remained for final determination by the Commission.

The here noted oral statement of counsel for Carter was clean-cut and distinctly posed the ultimate issue for decision as Carter would have the Commission see it. As we read its briefs on this review, counsel for the Commission does not aggressively part company with Carter's statement of the dominant and controlling issue before the Commission.

However, the Carter briefs on this review range over the entire body of testimony. Vigorous exception is generally taken to most of the ultimate findings of fact made by the Commission, and the basic argument is that in reviewing and analyzing the evidence and testimony in its aforesaid final Decision and Opinion rendered in 1956, the Commission did not squarely face up to the facts developed in the hearings, but to the contrary, it unfairly slanted its fact determinations thereby wilfully distorting the real fact picture presented by the testimony. On the basis of the expert testimony in the record, Carter indicts as grossly unfair and prejudicial the Commission's general comments on the testimony and evidence. It charges that the record there made by the Commission demonstrates its biased attitude, a condition which caused it to improperly and unjustly weigh the evidence and thereby deny Carter due process of law.

The final Decision and the final Opinion of the Commission occupy approximately 62 pages of the printed transcript. In these two pronouncements the Commission appears to have squarely met the domi-

1956. These findings are set forth in twenty separate and numbered paragraphs and the length of this instrument

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nating issue so clearly posed in Carter's final oral argument before the Commission. We think that the extensive and careful analysis given the testimony of certain of the most important expert witnesses serves to clearly indicate a sincere desire on the part of the Commission to reach to the heart of what Carter's counsel frankly assured the Commission in oral argument was the crucial issue for determination. We are convinced (as was the Commission) that Carter was trying to correctly identify the controlling issue finally tendered in this litigation.

Since we are convinced that the persuasiveness of the great mass of expert testimony and other evidence and the probative weight to attach to it, presented fact issues which were clearly for consideration of and determination by the Commission, we must and do conclude and therefore hold that the Commission acted well within the legitimate orbit of its fact finding powers when it determined, as facts, (1) whether or not the expert medical testimony and evidence, taken as a whole, compelled the conclusion that use of Carter's pills, as advertised, would in any way increase the secretion and or flow of liver bile, and thereby affect the human biliary system, (2) whether or not this same testimony and evidence, taken as a whole, established the existence of any relationship between bile flow and constipation which would or could be affected in any way by use of Carter's Little Liver Pills, (3) whether or not use of Carter's pills would (also) produce a beneficial effect "in the treatment of conditions, disorders and diseases of the liver." (As to point 3 here noted see Commission's Order set out in footnote 5, supra.)

Our comment on the position of Counsel for Carter calls for a further comment on assertions in the Commission's brief. Stress is there laid on the contention that "the actual area of factual conflict relates simply and solely to what influence, if any, petitioner's laxative pill will have on the production and flow of bile." The Commission's brief also emphasizes this point in somewhat different manner in stating that in Carter's (later noted) specification of errors 1 through 8, it states that the Commission's findings are erroneous because of the alleged method and manner in which the Commission considered or failed to consider the testimony and other evidence relating to experiments and tests conducted by witnesses for the Commission and for Carter. (See our comment on this point in footnote 4, supra.) The Commission's brief asserts that this evidence was admitted into the record as being responsive to allegations in the complaint that Carter's statement as to the effect of its laxative pill on the production and flow of bile was false and misleading. It is urged that as a consequence, Carter's specifications must, therefore, relate to the Commission's findings that Carter's laxative pill will have no effect on the formation or flow of bile. As respects this argument the Commission's brief contends that this is borne out by the argument in Carter's brief that there is no substantial evidence to support a Commission's finding that Carter's pill will have no effect

makes it necessary to summarize certain of the Commission's many fact determinations which we consider particularly pertinent to our present inquiry.

In footnote 9, infra, we have set out the text of the Commission's findings 3, 4, 18, 19 and 20 and these five

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upon the formation or flow of bile, i.e., that use of Carter's pills will not increase the production and flow of bile.

The Commission's brief also emphasizes the fact that the finding that Carter's laxative pill will have no effect upon the formation or flow of bile is only one of the many findings of fact made by the Commission relating to the falsity of petitioner's statements as to the therapeutic value of its laxative pill. Additionally, it is asserted that "there is no evidence of any nature in the record that any doctor has ever prescribed petitioner's laxative pill for any purpose other than to produce an evacuation of the bowels."

Counsel for the Commission content themselves with the ultimate argument that the only issues raised by Carter on this review are: (1) whether the findings that petitioner's laxative pill will have no effect on the formation or flow of bile is supported by the greater weight of the evidence and (2) whether petitioner was denied a fair and impartial hearing in this proceeding.

It is our considered judgment that the Commission reached its final determinations as to what had been established as facts, by a reliance on a body of testimony and evidence which it firmly believed to be substantial. As we have indicated, it then had before it for consideration not only the briefs and final oral arguments of counsel in 1956, but also the many thousands of pages of the reporter's transcripts of the testimony in the two sets of hearings held before the Hearing Examiner, along with more than 2000 exhibits of a highly technical character. We cannot find any legitimate basis for charging the Commission with dereliction of duty because it kept the analytical comments appearing in its Decision and Opinion within what we regard as a reasonable compass.

The Opinion of the Commission contains an illuminating and enlightening survey of the evidence and testimony as finally viewed by the Commission. This document, along with the Commission's comments on the evidence appearing in its findings of fact which are set out in its Decision, leaves no doubt in our minds that the Commission's final Decision (as averred in the Opinion) reflects the fact that its Decision represents "the result of its own exhaustive examination of the record."

It is also our conclusion from a careful appraisal of the entire record on this review that the Commission made and entered its final findings of fact and its final 1956 Decision, Opinion and Order based thereon, with a full understanding of the content and significance of the entire record in this case which was then before it. That the final oral arguments of counsel were made in May of 1956, and the Decision and Opinion of the Commission (which were entered in the first part of October 1956) bespeaks, if anything, a conscientious and painstaking examination and appraisal of the then record of monumental proportions before reaching the final conclusion announced in these two documents.

findings are not repeated at this point in our summary of other findings.

The Commission found as a fact (without dispute on this point) that the quantitative formula for Carter's medicinal preparation is

Podophyllum Resin U.S.P. 1/16 gr.
Po. Purified Aloes 1/4 gr.

It also found as a fact that Podophyllum Resin, also known as podophyllin, is used as a laxative, purgative or drastic cathartic, and aloes is one of the irritant catharties ranking with senna, rhubarb and cascara sagrada; that Carter's preparation serves to increase temporarily the motility of the large bowel by irritation and thus induces partial evacuation of the large intestine.

The Commission, inter alia, also found that in connection with the sales of its laxative pills, Carter had represented to the purchasing public that its said preparation (1) represents a fundamental principle of nature in self-treatment; (2) is a competent and effective treatment for "a sluggish liver"; (3) will "wake up the flow of bile," is "effective in making bile flow freely"; (4) will cause the proper flow of gastric juices, vital digestive juices and vital alkaline juices; (5) is based on the fundamental principle of the operation of the digestive system, will "help food digestion," "lessen food decay," regulate digestion and the digestive system; (6) restore regularity, is a cure and remedy and constitutes a competent and effective treatment for constipation; (7) will clear away the "dark clouds of listlessness and despondency" and "give one's personality a chance"; (8) will "keep up one's pep and vigor," "make one feel good and up to par again" and "keep one smiling and happy"; (9) will eliminate bad disposition and keep good dispositions "cheerful, happy and a regular thing"; (10) will help in more ways than one to make one feel better again fast and differently and will pro-

vide two way relief; (11) follows nature's own order for regularity and so regulate the digestive process that if taken at night one will awaken feeling the way one wants to feel, "full of normal old-time pep and vigor," "alive," "alert," "cheerful," "peppy," "eager," "robust," "bright," "lively," "full of pep," "bounce," "energy," "springy," "snap," "go and vigor," "spry and chipper again," "perked up," "up on your toes," "up to snuff," "up to par again," "fit as a fiddle," "chipper as a chipmunk," "on top of the world," "up and up," "rarin' to go," ready to "jump out" or "roll out" of bed, "singing like a lark," "singing a song for the sheer joy of living," "fresh as a daisy," "glad to be alive," "ready for a big breakfast"; (12) will influence the flow of liver bile so that one can overeat and overindulge without any discomfort and if one has overeaten or overindulged it will overcome such discomforts and enable one to wake up, "roll out of bed," "rosy and bright," "clear-eyed and steady-nerved," "feeling just wonderful," "feeling like a million," free from that "blue Monday feeling," "ready for a great big breakfast," "alert and ready for work"; (13) does not contain any strong medicine and is safe to use; (14) is a competent and effective treatment for the mental and physical disorders set forth in paragraph Seven of the complaint (see our summary of the allegations in this paragraph referred to supra in this opinion); (15) *will have therapeutic value in the treatment of disorders and diseases of the liver.*

Upon consideration of the entire record before it, the Commission further found that the advertising representations of Carter, as just above summarized, were false and misleading in material respects. It also specifically found that through advertising which used the word "Liver" in the name "Carter's Little Liver Pills," Carter thereby represented that its preparation would have some therapeutic action, effect and influence on the liver, and is for use in the treatment of conditions, disorders, and diseases of the

liver, and that such a representation was false and misleading.

The Commission's finding as to the false and deceptive character of the advertising representations made by Carter was based on its further findings that "Inasmuch as the laxation afforded by an irritant laxative or cathartic is not a normal physiological method of evacuation and is not based on any principle having relation to natural bowel motility, it is not true that the preparation represents a fundamental principle of nature in self-treatment." This finding in turn was based on the evidence of a witness supporting the Commission's complaint, and of several doctors who testified for Carter.

The Commission also found that "In a scientific sense, constipation is a term used to connote a slower rate of evacuation of the large bowel than the one normal for that individual. Although it has reference to delay in the passage of indigestible residues through the alimentary tract and to infrequency of bowel action, and may be used to describe the condition in which the stools are dry and hard; constipation has been described also as being that condition which causes a person to believe that a cathartic is necessary to cause a bowel movement. Normal frequency in bowel movement varies widely among individuals. Because varied notions obtain with respect to what represents normal frequency, the average layman may not diagnose constipation properly and there is a tendency for self-diagnosis to be made on the basis of symptoms having no relationship to constipation. In its chronic form, there are two general types of constipation: (1) spastic, and (2) atonic. The state of the musculature of the large bowel differs in the two conditions named. In the spastic variety, the musculature is abnormally contracted and rigid and does not propel the contents thereof forward in a normal manner. In the atonic condition usually associated with an enlargement of the large bowel due to tremendously increased con-

tent, the musculature does not contract and retain its tonus or state of partial contraction. Atonic constipation is attributable to constitutional weakness of the muscles of the colon and is supposed to occur principally in the rectum, while the spastic type is supposed to be due principally to anxiety, worry, or nervous strain. Among the causes of constipation or irregularity of bowel movement are improper diet and stool habits, insufficient intake of fluids and variations or obstructions of the alimentary tract such as fissure, cancer and debilitating conditions. Factors predisposing to constipation are numerous and thorough study by the physician is necessary before comprehensive treatment is undertaken. Its treatment, therefore, varies in individual cases, but is directed to correcting the basic conditions which are responsible." (As to the fundamental propositions noted in this finding, the several doctors who testified appear to be in agreement.)

The Commission further found that with regard to the type of constipation known as spastic, Carter's Little Liver Pills "will tend to aggravate any state of spasticity which is present." The Commission also found on undisputed evidence that the habitual use of irritant laxatives and cathartics tends to produce irregularity rather than to restore regularity and the use of Carter's preparation will not restore regularity of bowel movement.

The Commission also found (without dispute) that the statements appearing in Carter's advertising to the effect that its product is composed of two simple vegetable medicines and the references therein to "gentle action purportedly afforded by its use" imply that Carter's Little Liver Pills do not contain strong medicines.

The Commission found (and we think correctly) that Carter's pills do contain "strong medicines." The Commission declares, and the record shows, that though the ingredients of these pills are obtained by purification of members of the plant kingdom, their ingredients are "irri-

tant purgatives." This record also provides substantial evidence that aloes taken in sufficient amounts leads to some hyperemia and increased vascularity; that neither aloes nor podophyllin is absorbed to any great extent, and as long as they remain in the colon may be causative of local irritation. It also found (in the first series of hearings) that podophyllin was removed from the U. S. Pharmacopoeia when the scientific group responsible for the preparation of this publication recognized it as a "drastic," or member of that class of irritant drug which includes colocynth and jalap.

The Commission also found (without dispute) that Carter's product is not safe for and harmless to all individuals who are constipated or suffering from delay or irregularity of bowel movement and symptoms thereof, or from failure of digestion. It also found (without dispute) that Carter's pills are potentially injurious if taken by persons suffering from abdominal pains, nausea, vomiting, or other symptoms of appendicitis. It further found (without dispute) that use of Carter's pills may cause perforation of the intestine in instances where delay in the evacuation is due to obstruction in the tract. (It was emphasized in the evidence that in some instances the use of Carter's pills may be attended with griping and stomach discomfort, and when used in the presence of constipation of the *spastic* type may serve to increase and aggravate such state of spasticity).

The Commission also found, and the evidence is uncontradicted, that use of a laxative is contraindicated in many conditions.

It also found specifically that the ingredients in Carter's pills, alone or in combination of one with the other, will have no therapeutic action, effect, or influence, corrective or otherwise, on the liver. This finding rests upon the testimony of three experts whose testimony supported the allegations of the Commission's complaint.

The Commission also found that the greater weight of the testimony and other evidence introduced in the record supports informed determinations that Carter's preparation will not stimulate the formation of bile by the liver or increase the secretion of bile by the liver.

It also found, inter alia, that Carter's preparation will not increase the flow of bile or any constituents thereof into the duodenum—also that Carter's preparation is not an effective treatment for sluggish liver function and will have no therapeutic action on the liver or diseases thereof; that it will not wake up the flow of bile or cause bile to flow freely, or favorably influence the formation or flow of bile either as to quantity or the vital and effective constituents thereof; (As pointed out in footnote 7, supra, the vital controversy in this case centers in this area.[8]) that this

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[8] Certain of the Commission's expert medical witnesses testified that Carter's laxative preparation would have no influence on bile flow.

Certain of Carter's expert witnesses differed somewhat in their views on this particular problem; one expert medical witness testified on direct examination that Carter's laxative pill would effect bile flow; one of such witnesses said that his experiments would not permit a conclusion, and a third medical expert (characterized by Carter in its brief as its "key witness") said that Carter's pill would increase bile flow if three conditions were present at the same time.

The "three conditions" mentioned by this third witness were as follows: (1) Carter's pill must be taken in sufficient doses over a sufficient period of time to "produce laxation either within normal limits of fresh weight stools or the maximum effect." This witness stated that to accomplish this, 5 of Carter's pills must be taken every day for 1 week. He admitted that what is a normal limit of fresh weight stools varies in the individual from time to time. He stated that he was not willing to say if a person met this requirement that it would mean the flow of bile would be increased. (2) As to the second "condition," this witness stated that "the rate of flow of bile into the duodenum will be increased in individuals and, only in individuals who show during periods within which they have been taking no [Carter's laxative] pill 'low values' for the biliary constituents in the duodenal fluid in response to a stimulus introduced into the duodenum of the type of Peptone."

As to the way this (second) condition could be met, the expert admitted that unless the purchaser of Carter's pills had had a duodenal drainage performed, he would not know whether such drainage was high or low and unless he did know, he would not be in a position to tell whether Carter's pill would have any effect upon the flow

preparation does not provide two-way relief and has no therapeutic effect beyond that of an ordinary laxative, that is to say, of any substance which increases the movements of the large bowel either through irritation, bulk or fluid content; that it will not influence the production of flow of liver bile so that an individual can overeat and overindulge in "good times" without such discomforts as may normally attend them, nor enable an individual to wake up "clear-eyed and steady nerved," "feeling just wonderful," and "alert and ready for work"; that Carter's preparation has no chemical action on food which will prevent decay thereof, and the representation that it will lessen food decay is misleading.

It also found that use of Carter's product will not increase the effectiveness of the gastric juices or cause the proper flow of any of the vital digestive juices, and it will not help digestion or regulate the digestive system or digestion, or have any salutary effect upon the gastro-intestinal tract aside from affording temporary partial evacuation of the colon; that to the contrary in some instances, use of Carter's pills may interfere with and disturb digestion.

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of bile. Again, this witness was not willing to say that even though this second condition was met together with his other "conditions," Carter's laxative pill would secure an increase in bile flow.

The third condition was that Carter's pill will increase the flow of bile "in individuals who show signs, during periods in which they are not taking Carter's pills, of diminished rates of intestinal motility as indicated by abnormally low fresh weight stools and symptoms depending upon the abnormally low rate of intestinal motility."

Counsel for the Commission finds this testimony concerning the third condition to be "difficult of interpretation" and points out that Carter's witness interprets it to mean "that the individual be one who shows signs when not taking the pills of low or diminished rates of intestinal motility as indicated by abnormally small stools or absence of stools."

On cross-examination, this "key witness" of Carter was asked whether, if these "three conditions" he had named were met, he was willing to state that whenever anyone takes Carter's Little Liver Pills, (under these three conditions) the level of the flow of the biliary constituents into the duodenum would be raised. The witness replied that he was not willing to make such a statement.

The Commission went further and found that when certain conditions exist that are associated with constipation, Carter's pills do not constitute a competent and effective treatment for such manifestations (referred to in finding No. 4—see footnote 9 infra) when they are associated with or caused by constipation; that Carter's preparation is not an effective treatment for indigestion, or "lazy digestion" or retarded digestion in any circumstances in which such conditions may occur.

Based upon its consideration of the evidence as a whole, and its appraisal of the weight to be given the probative value of all of the evidence and testimony adduced in the many hearings over the years, the Commission also found, inter alia, that evidence introduced in support of the complaint, particularly when considered in connection with the results afforded by certain of the scientific experiments, constitutes a full refutation of the scientific view by witnesses for Carter to the effect that "a favorable influence on bile flow may result from the increased intestinal motility afforded by the irritating action of a laxative" of the Carter type. It also found that "not only is it apparent that the augmented intestinal motility through this (Carter) type of laxative affords bowel evacuation does not significantly increase bile flow, but the greater weight of the scientific evidence received shows that there is no causal relationship between constipation and bile flow"—that "this conclusion has support in other scientific evidence indicating that constipation will not, under any circumstances, decrease bile in the system to such an extent that there is not sufficient bile to carry on its function in the digestive process."

The Commission further reached and expressed the factual conclusion and opinion on the entire record before it, "that the greater weight of the testimony and other evidence introduced into the record supports informed determinations that the preparation Carter's Little Liver Pills will not stimulate the formation of bile by the liver or

increase the secretion of bile by the liver"; that "inasmuch as the evidence further shows that the respondent's product will not cause the gall bladder to contract or cause relaxation of the sphincter of Oddi or prevent its contraction in the first instance or serve in any way to milk bile from the ampula of Vater or the bile duct, the Commission further concludes that the respondent's preparation will not increase the flow of bile or any constituents thereof into the duodenum."

In Paragraph 12 of the Findings the Commission found that "Counsel supporting the complaint maintains that the evidence relating to the test studies submitted in support of the complaint conclusively establishes that Carter's Little Liver Pills do not act in any way to increase the secretion or flow of bile. In contending that the greater weight of the evidence fully supports determinations to the contrary, counsel for the respondent asserts that the record shows that a relationship exists between constipation and bile flow in that a large number of people who suffer from constipation also have a subnormal flow of bile; and that, concomitant with the laxation afforded them and the relief of their associated symptoms, the (Carter) preparation causes significant increases in the levels of biliary constituents for these individuals. *Each counsel contends in effect that the scientific evidence presented by his adversary is based on defective experimental procedures and reflects erroneous interpretations of those studies and unsound expressions of medical opinion.*" [Emphasis supplied.] See our comments in footnote 4, supra, concerning these "experimental procedures." (See reference in footnote 9 to text of Commission's Finding No. 19 in which it dismisses certain charges in its Complaint.)

The Four Controlling Findings

Four of the Commission's final findings of fact here noted require special emphasis by us, this for the reason

that they clearly indicate that the Commission finally elected to support the injunctive provisions of its Cease and Desist Order of October 4, 1956 (footnote 5) by an ultimate reliance on the facts which the Commission, in and by these particular findings, determined had been fully and finally established by a body of evidence of a substantial character. In the margin we set out the text of the four crucial findings of fact here referred to.[9] The language of

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[9] Finding No. 3 reads as follows:

"In furtherance of the sale and distribution of the aforesaid medicinal preparation, the respondent has disseminated, and has caused the dissemination of, advertisements concerning said preparation by the United States mails and various means in commerce, as 'commerce' is defined in the Federal Trade Commission Act; and the respondent has disseminated, and has caused the dissemination of, advertisements concerning such preparation by various means for the purpose of inducing, and which have been likely to induce, directly or indirectly, the purchase thereof in commerce, as 'commerce' is defined in the Federal Trade Commission Act."

Finding No. 4 reads as follows:

"All the representations hereinafter referred to have been made directly or by implication in advertising material which the respondent has disseminated or caused to be disseminated in the manner noted in the preceding paragraph. [The preceding paragraph is Finding No. 3.]

"(a) Through use of words, phrases and statements purporting to be descriptive of the therapeutic value, beneficial effects and advantages afforded by use of the preparation 'Carter's Little Liver Pills,' the respondent has represented, directly and by implication, among other things, that its product represents a fundamental principle of nature in self-treatment, that it is a cure and remedy and constitutes a competent and effective treatment for constipation, and will bring on, help, and restore regularity of bowel movement.

"The respondent also has represented that its preparation does not contain any strong medicine, and that it is harmless and safe for use by those individuals who have constipation or are experiencing delay in bowel movement or in whom a failure to digest food has occurred.

"(b) The respondent similarly has represented that the preparation is a competent and effective treatment for sluggish liver function, liver ills, and disorders affecting the liver; that its use will 'wake up the flow of bile,' will make 'bile flow freely' by getting the liver back to normal and back to producing; that its use will so influence the production or flow of liver bile that one can overeat and overindulge in 'good times' without the ordinary discomforts result-

Finding No. 20 serves to further clearly identify the particular advertising representations employed by Carter in

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ing therefrom; that if one has overeaten and overindulged in 'good' times' that the preparation 'Carter's Little Liver Pills,' by its influence on the production or flow of liver bile, will overcome the discomforts that usually and ordinarily follow such indiscretions and will enable the user to wake up 'clear-eyed and steady-nerved,' 'feeling just wonderful,' and 'alert and ready for work'; that such preparation through its favorable influence on bile flow and in helping to restore regularity provides two-way relief, and that it is not an ordinary laxative but possesses therapeutic properties over and above and in addition to its laxative action.

"(c) The respondent's advertising also has contained statements representing that use of its preparation will cause the proper flow of the gastric juices and natural vital digestive juices; that it will lessen food decay and is based on the fundamental principle of the operation of the digestive system; that such preparation will help food digestion, including the stopping of fatty indigestion, and will regulate digestion and the digestive system; and that it so follows nature's own order for regularity and so regulates digestion that it will make the user 'fit as a fiddle,' and full of 'bounce.'

"The respondent further has represented that constipation poisons the body.

"(d) Through the use of colloquial words and phrases, which purport to be descriptive of various physical and mental conditions, the respondent has represented, directly and by implication, among other things, that when caused by constipation or irregularity of bowel movement, the preparation designated 'Carter's Little Liver Pills' is a competent and effective treatment for those conditions in which an individual feels: 'Down-and-out,' 'blue,' 'down-in-the-dumps,' 'worn out,' 'sunk,' 'logy,' 'depressed,' 'headachy,' 'sluggish,' 'all-in,' 'listless,' 'mean,' 'low,' 'cross,' 'tired,' 'stuffy,' 'heavy,' 'miserable,' 'sour,' 'grouchy,' 'bilious,' 'irritable,' 'cranky,' 'peevish,' 'fagged out,' 'dull,' 'sullen,' 'what's-the-use,' 'bogged down,' 'grumpy,' 'run-down,' and 'gloomy.'

"The respondent similarly has represented that its product is a competent and effective treatment for headache, ugly complexion, bad breath, coated tongue, bad taste in the mouth, 'lazy digestion,' and 'indigestion,' when caused by constipation."

Finding No. 18 reads as follows:

"Through use of the word 'Liver' in the name 'Carter's Little Liver Pills' which is featured in the advertising, the respondent represents, directly and by implication, that the preparation 'Carter's Little Liver Pills' will have some therapeutic action, effect, and influence on the liver, and is for use in the treatment of conditions, disorders, and diseases of the liver. Said representations are false and misleading. The ingredients in the preparation 'Carter's Little Liver Pills,' alone or in any combination of one with the other, will have no therapeutic action, effect, or influence, corrective or other-

the sale of its product (which the Commission ultimately condemned as false and misleading) these including the

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wise, on the liver. The preparation will have no therapeutic value in the treatment of any condition, disorder, or disease of the liver or the biliary system. Upon consideration of the remedy which should be applied in this connection, the Commission is of the opinion that only excision of the word 'Liver' from the product name will serve to eliminate the deception engendered by its use."

Finding No. 20 reads as follows:

"The Commission, therefore, finds that **the representations appearing in the advertising** for the preparation 'Carter's Little Liver Pills,' **as set forth in Paragraph Four and Paragraph Eighteen hereof,** are misleading in material respects, and that the advertisements **thus disseminated by the respondent Carter Products, Inc.,** constitute 'false advertisements,' as that term is defined in the Federal Trade Commission Act. **The use of such representations and of the word 'Liver'** in the name 'Carter's Little Liver Pills,' by the respondent has had, and now has, the tendency and capacity to mislead and deceive a substantial portion of the purchasing public into the erroneous and mistaken belief that **all such statements and representations** are true, and to induce a substantial portion of the purchasing public, because of such erroneous and mistaken belief to purchase the respondent's preparation." (Emphasis is ours.)

In addition to the Commission's "four controlling findings" above referred to the Commission made Finding No. 19 which is favorable to Carter. This particular finding reads as follows:

> "(a) The complaint charges also that the respondent's advertisements constitute false advertisements for the further reason that they fail to reveal certain facts as to potential dangers inherent in the use of such preparation under conditions described in the advertisements or conditions as are customary and usual by persons suffering from abdominal pains, nausea, vomiting, or other symptoms of appendicitis. The Commission is unable to find, however, that the potential danger to the public health inherent in the use of the respondent's preparation is so serious as to require a disclosure in the advertising of the matters to which this charge relates and, in the circumstances, is of the opinion that dismissal of such charge without prejudice is warranted.
>
> "(b) Additional allegations of the complaint charge that the respondent has falsely represented that calomel is a drastic and dangerous laxative compound, the use of which is an ordeal. Although testimony was introduced into the record directed to showing, among other things, that calomel, when taken in proper doses, would not be painful, it is not believed that the charges are supported by the record, and they are, accordingly, dismissed."

advertising representations carefully described in Findings Nos. 4 and 18. (Among these false and misleading advertisements is the use of the word "Liver" in the name "Carter's Little Liver Pills.") Finding No. 3 describes these advertising representations as having been disseminated in commerce.

Since the Commission saw fit in these four findings to specify the ultimate basis for its Order here assailed by Carter, we think that by this action the Commission has materially narrowed our task in reviewing the record. As we view the problem now before us, it is whether the record of evidence and testimony, taken as a whole, presents a body of evidence of a substantial character which provides support for these particular findings of fact. If so, they must be sustained.

In appraising the entire record we were at pains to examine the testimony of the array of witnesses produced by the parties. In so doing we noted the weight which the Commission saw fit to give the various conflicts in the testimony of the several witnesses for both sides as well as to the points of agreement developed in their testimony, a fact to which we have previously adverted. And we think that in view of the great length of this record (including the exhibits) and the complexities enshrined in its mass of highly technical testimony from experts, the Commission is not to be criticized for refraining from engaging in a lengthy recital and appraisal of every facet of this extensive testimony, as buttressed by the exhibits. From our consideration of the record we are fully persuaded that the Commission did carefully and conscientiously consider and appraise the probative force of the entire body of testimony and evidence before entering the Order here assailed. In our judgment its final pronouncements in its decision and formal opinion bear witness to that sort of treatment.

When Carter made the representations as to the therapeutic qualities and effect of its pills in the advertising

claims particularly described in Findings Nos. 4 and 18, it was therein making statements of fact, and the truth or lack of truth in these representations presented an issue of fact to the Commission. Carter has vigorously assailed the Commission for referring to the "inconclusive" and or "impersuasive" character of certain phases of the testimony presented by it; and charges that the record shows that this kind of a conclusion was the result of faulty evaluation of the evidence. The burden of proof was on the Commission, and its legitimate administrative task was to primarily determine, as it did, whether the probative weight of the proof submitted in Carter's defense served adequately to rebut the proof presented by witnesses supporting the Commission's complaint. Whether Carter's evidence was sufficient in this respect presented a question of fact primarily for the Commission to decide from the entire record. The duty of the Commission was to weigh all of the evidence before it, and in so doing to determine therefrom whether *all or any part* of this evidence was convincing in its probative weight or was so inconclusive or unconvincing as to lack the probative weight necessary to carry conviction of its truth. We think that in expressing its determination as to the proper weight to be given the entire body of evidence, the Commission did not err in employing our common vernacular to describe the definite impression this evidence established in the minds of members of the Commission.

As a final comment on the four crucial findings here mentioned, it should be noted that so far as concerns Carter's far-reaching advertising claims in evidence, the record clearly indicates that the several claims described in Findings Nos. 4 and 18 are fairly typical of, and embrace many of the aggregate of Carter's advertising claims as to the therapeutic qualities of its product, all as set forth and described in several other findings of fact entered by the Commission which are supported by substantial evidence.

We think that the evidence introduced to show that the claims described in Findings Nos. 4 and 18 had been made in Carter's extensive advertising, was most substantial in character. Our conclusion is that by Findings 4, 18 and 20 the Commission made plain that in the last analysis it elected to rest its injunctive Order of 1956 on Carter's use of the particular advertising claims so carefully identified in these critical findings.

CARTER'S SPECIFICATION OF ERRORS

On this review on the merits, Carter's Specification presents twelve claims of error on the part of the Commission. It accompanies these claims with a brief preliminary comment charging that *the record itself* demonstrates that the Commission committed *all* of the errors relied on in this Specification, and that the Commission's proof does not in fact or in law constitute substantial evidence including conviction sufficient to warrant the issuance of the Commission's Order.

Before reaching Carter's Specification and the supporting argument in the briefs, we note the fact that Carter (also) supports the said claims of error by reference to, and adoption of, its formal "Petition to Review and set aside the Commission's Order" and its "Petitioner's statement of Points." In the margin we note some of the salient points raised in these documents.[10] These points are keyed to the

[10] In its "Petition to Review" here noted, Carter, inter alia, complains that on March 3, 1955, the Hearing Examiner entered his order closing the case; that Carter then moved the Commission to disqualify this hearing officer and terminate the entire proceedings; that before the Commission could decide this motion, the said officer filed his Supplemental Report with respect to the proceedings on remand from this court and recommended the issuance by the Commission of the Cease and Desist Order now before this court; that on September 20, 1955, the Commission denied Carter's motion to disqualify the said Hearing Officer and also refused to grant the relief sought in Carter's said motion; that an appeal was taken on November 29, 1955 to the Commission from the rulings and Supplemental Report of the Hearing Examiner on which the motion to

general arguments in Carter's briefs in support of its formal Specification of Errors.

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disqualify him was rested; that the Commission thereafter issued its Cease and Desist Order of October 4, 1956 which is now before us.

In summary, the grounds for relief asserted by Carter in its said "Petition to Review" are as follows:

The Commission's said Cease and Desist Order, and its aforesaid order of September 20, 1955, along with the Decision and findings of fact "are erroneous in law and fact, not supported by the evidence, or by any probative evidence or by substantial evidence;" are contrary to the evidence and the weight of the evidence; are violative and in excess of the Commission's statutory and jurisdictional powers; are violative of Carter's constitutional rights; are contrary to the Federal Administrative Procedure Act; are not in the public interest and are (also) contrary to the mandate of this court heretofore issued; that the aforesaid Cease and Desist Order of the Commission and its denial of the aforesaid motion of Carter are (also) based upon the failure of the Hearing Officer and the Commission "to weigh, consider or receive the competent, material and relevant evidence offered or adduced in these proceedings."

Carter further complains therein that the Commission did not pass "properly" upon its exceptions and proposed findings of fact and conclusions of law; that as a consequence Carter was deprived of due process and fair and impartial trial on the entire record made in both sets of hearings.

Petitioner's "Statement of Points" contains a vigorous attack upon the validity of the proof tendered by the Commission's witnesses, and the Decision and Opinion of the Commission resting on this proof. It is urged that the said Decision and Opinion are "irresponsive" to Carter's claims; are contrary to the evidence and weight of evidence, and are not supported by reliable, "convincing," probative or substantial evidence, or such evidence "as a reasonable mind might accept as adequate to support a conclusion," or as would logically and rationally permit findings to be made," and are not supported by proof of (and contrary to) the consensus or general agreement or qualified medical opinion. In short, the charge of Carter in his pleading is that the Commission's findings of fact, its Decision and Opinion are, on their face, and inherently, self-destructive and self-contradictory of each other, and on their face, demonstrate the Commission's failure to sustain its burden of proof and convincingly show that the Commission "has never weighed, considered or passed upon this record" in accordance with the letter and the spirit of the mandate of this Court.

It is further urged in these "Points" that the Commission has not subjected the record to "any proper scrutiny at all" in that it failed to pass separately, fairly and carefully upon all of Carter's original and supplementary exceptions and proposed findings.

Carter's "Statement of Points" is lengthy, and is set forth in nineteen paragraphs. It is in the main a vigorous frontal attack on

Carter's claims of error are supported in two briefs containing 215 pages of argument and citation of approximately 206 cases thought to be pertinent to the issues presented in this review. Statutes and text matter are also cited as authority. We set out in the margin the text of the *first six claims* of Carter's Specification of Errors.[11]

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the testimony and proof tendered by witnesses supporting the Commission's complaint. It challenges the validity of the proof dealing with so-called "experimental proof" and the opinion evidence given by the Commission's witnesses in connection therewith. It likewise asserts that the testimony of the Commission's witnesses did not constitute proof by "general medical agreement" or "consensus of medical opinion"—that proof that Carter's "honest, harmless therapeutic claims" were false was not established as required in this type of conflict.

It is obvious that the above noted reference to the "honest, harmless therapeutic claims" of Carter is a comment upon the many claims asserted in the advertising material disseminated by Carter.

[11] "(1) the Commission's findings disregard the testimony and express admissions (unreported in its findings) of its **own** witnesses that their abnormal surgically performed test methods, employed primarily on **animals**, either changed entirely the physical conditions or did not reproduce conditions which could be properly compared to the normal conditions of use of Petitioner's product;

"(2) the Commission's findings disregard the testimony and ignore express admissions (unreported in its findings) of its **own** witnesses that the protocols of **all** their tests, whether upon animals **or** humans, were patently and fatally faulty in design and their tests themselves both fatally defective and irresponsive to Petitioner's claims;

"(3) the Commission's findings disregard the testimony and ignore express admissions (unreported in its findings) of its **own** witnesses (destructive of their test procedures), that **dosages** of various drugs or the same drugs in animal and man are not comparable and introduce a disturbing variable which renders the Commission's evidence unsubstantial;

"(4) the Commission's findings disregard and ignore testimony and express admissions (unreported in its findings) of its **own** witnesses that under the 'abnormal condition of the experimentees' the reactions of man and animal to the same or similar drugs are not identical or substantially identical and require to be supplemented by experimentation on representative groups of normal human beings;

"(5) the Commission's findings disregard and ignore the testimony and express admissions of its **own** witnesses (not reported in

Carter's arguments supporting these six claims emphasizes, and to a marked degree appears to be predicated upon, the assumption that the Commission's final (1956) administrative findings of ultimate probative facts in this case are fatally tainted and should and must be rejected on this review as invalid because *portions* (or possibly *all*) of the actual testimony of some of the Commission's witnesses was (to quote Carter) "unreported in its findings," that is to say, such testimony was not set out verbatim in the Commission's findings of fact. If it be Carter's theory that in order to be valid and be tolerated in this court the Commission's findings of fact should repeat part, or all, of such testimony, we must and do reject such a theory as lacking validity under established practice in our system of law. And it should be added that our attention has not been drawn to any responsible authority which gives sanction to such a theory concerning the fact-finding functions of an administrative tribunal like the Commission.

We summarize in the margin[12] the remaining six claims of error asserted by Carter.

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its findings) that because of the concededly delayed reaction time of the drugs tested, the Commission's experiments were on their face prolonged for an insufficient length of time to constitute substantial evidence inducing conviction that those drugs do not possess the effects claimed by Petitioner;

"(6) the Commission's findings disregard and ignore the testimony and express admissions by its **own** witnesses (not reported in its findings) that their liver function tests performed on animals are not translatable to man;"

[12] The Commission's findings (1) are mutually self-destructive and self-contradictory because the very same defects which they impute to Carter's experiments in order to disqualify those experiments "by the same token destroy the Commission's own experiments," thus, on their face they demonstrate that the experiments of the Commission's witnesses "cannot possibly constitute substantial evidence inducing conviction"; (2) the findings are based on an erroneous and illegal standard of proof imposed on Carter alone, namely, that its proof be conclusive, thus applying a dual standard of proof, one for its own and another for Carter; (3) the findings (a) were arrived at by "ignoring the spirit and purpose" of this court's remand by excluding proper offers of proof, by prejudiciously

Before leaving the subject of Carter's claims of error, we point out that after our remand, the cross-examination of Commission witnesses Doctors Case and Bollman was resumed (on the 146th hearing in this prolonged litigation which had then spawned a transcript of record containing approximately 13,000 pages). This appears from a statement by the Hearing Examiner. See also footnote 15, infra. The cross-examination of both of these witnesses was searching and extensive. Including a re-direct examination by Commission counsel, this part of the record occupies about 300 pages of the printed transcript now before us. A reading of this segment of the huge record induces our belief

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restricting, through its Examiner, the cross-examination of Commission's witnesses designed to test the experiments of these witnesses, and by erroneously restricting Carter's examination of its own expert witnesses for the purpose of explaining or amplifying their experiments; (b) are based upon the misconduct of these proceedings by an Examiner whose bias and prejudgment of the issues have now been demonstrated beyond question, and show that the Commission shared the prejudgment and failed to make a fair estimate of the worth of the testimony; (c) were based on its reversible error in denying Carter's motion to disqualify the Examiner and (d) establish beyond question that the Commission has again denied Carter due process of law; (4) that the issues involve a medical field—the liver and biliary system—which is one of the most problematical controversial and highly unsettled frontiers in the whole realm of medicine and where due process demanded of the Commission, before snuffing out Carter's huge investment and property in this product, particularly high and exacting methods of modern and up-to-date scientific proof and an evaluation based on a disinterested inquiry in the spirit of science; (5) the defects in the Commission's proof are so gross and its misjudgment of that proof so great that it is unnecessary to review Carter's evidence presented in defense, because there has been so clear and so glaring a failure on the part of the Commission to sustain its affirmative burden of proof, and because the Commission made a wholly erroneous disposition of that evidence throughout its Findings which deprived Carter of due process; (6) that however the evidence is viewed, impelling and important constitutional considerations, involving novel questions of law, preclude the issuance in this case of any cease and desist order at all.

In presenting the six claims of error just above noted, Carter assails the Commission's findings because they did not contain an "express finding" that Carter's experimental proof does not constitute substantial evidence, the findings only stating that such proof was "not conclusive."

that Carter's questions on cross-examination after the remand reached into every material phase of the crucial issues present in this case, including a re-examination by Carter of certain views and opinions expressed by these two Commission witnesses in the testimony they had given in the prior series of hearings.

As to the breadth of allowable cross-examination here referred to, the Hearing Examiner stated to counsel in the case that he was "going to give the respondent (Carter) as full leeway as I possibly can irrespective of any objection of the attorney in support of the complaint," this so that counsel might "pursue this cross-examination until he can go no further." At the conclusion of the testimony of Dr. Case, counsel for Carter was asked by the Hearing Examiner if he was satisfied that he had been given ample opportunity to cross-examine this witness, and counsel then stated that he had asked all of the questions he wanted to ask.

At the conclusion of all of the testimony of Dr. Bollman, counsel for Carter stated that he had no further questions.

Bollman was extensively questioned by Carter's counsel as to the *method* he employed in conducting his animal experiments. He was asked to compare his views and supporting data with certain views he had previously expressed, and to justify his views in light of conflicting views expressed by Carter's witnesses and certain other experts. The cross-examination was so thorough and searching that it would be difficult to envision a more complete exploration of professional opinion dealing with a highly technical subject upon which differences of opinion had been developed. In any event, whether Bollman used a *correct method* in experimentation was a factual question for decision by the Commission when it weighed the evidence. See our comments in 201 F.2d 446, 449, 450.

Under the decisions later noted it will not be contended that it is the duty of this Court to weigh the evidence before

the Commission and or choose between inferences which might arise from an appraisal of the probative worth of this evidence, since exercising those important functions became the primary duty of the Commission. We agree with Commission counsel that it was for the Hearing Examiner and the Commission, not the Courts, to pass upon the credibility of witnesses and the weight to be accorded their testimony. See decision of this Court in Tractor Training Service, et al. *v.* Federal Trade Commission, 227 F.2d 420, 424. See also Corn Products Refining Co., et al. *v.* Federal Trade Commission, 324 U. S. 726, 739. Many decisions of like purport fully support this well established rule. So much may also be said concerning the *weight* to be given by the Commission to the facts and circumstances admitted as well as inferences reasonably to be drawn therefrom. The possibility of drawing either of two inconsistent inferences from the evidence does not prevent the Commission from drawing one of them.

The overwhelming mass of evidence and testimony in this case dealt almost exclusively with not only highly technical problems in the field of medicine, but also with what we regard as pure questions of fact—(1) what therapeutic action, effect or influence, if any, would the use of Carter's preparation have upon the human liver or diseases thereof, (2) would use of Carter's preparation stimulate the formation of bile by the liver or increase the secretion of bile by the liver, (3) what therapeutic effects, if any, followed the use of Carter's preparation when employed by human beings for the purpose of securing satisfactory relief from the array of human ills and achieving the many physical benefits so vividly described and promised in Carter's widely diffused advertising?

We are quite convinced that answers to such technical questions in the field of medicine could come only from medical experts. Their testimonial conclusions and opinions as to the effect upon the human system arising from

the use of Carter's preparation had to rest upon and derive from their "experiments" (later referred to); their knowledge of the character and therapeutic qualities of the two drugs used in Carter's preparation; their own practical professional experience, and upon medical texts and technical opinions of other medical experts which appear to have found their way into the testimony. Confronting the record as a whole, including the testimony from all medical experts, the Commission faced the duty of concluding and determining from this body of evidence just what medical facts had been established as true by evidence of a substantial character.

As to the experiments above referred to, Commission finding No. 11 makes plain that expert witnesses for *both sides* had extensively experimented upon anesthetized dogs and human beings to demonstrate the results on these animals from use of the drugs employed in Carter's pills, or from use of drugs possessing similar characteristics. The elaborate testimony of these witnesses, with supporting data, was received in evidence to support the basic contentions of both parties as to results achieved from such experiments. In its Finding No. 12 the Commission was at pains to find that "each counsel contends in effect that the scientific evidence presented by his adversary is based on defective experimental procedures and reflects erroneous interpretations of those studies and unsound expressions of medical opinion." The lengthy comments of the Commission in its findings dealing with the testimony of expert witnesses concerning results of their experiments on dogs and human beings convinces us that this phase of the evidence and testimony was given a searching and conscientious study by the Commission before it made its final findings of fact. (See our comments in footnote 4, supra, concerning our first opinion which dealt with admissibility of evidence and testimony relating to such experiments.)

Opinion of Ninth Circuit Court of Appeals
Filed June 16, 1959.

In its attack on the substantiality of the Commission's evidence, Carter vigorously argues that the testimony of the expert witnesses presents a conflict of general informed medical opinion on basic medical issues; that this conflict is so substantial "as to compel enforcement by this Court of the standard of certainty in the proof of the falsity of a harmless, honest therapeutic claim prescribed by the Legislature in enacting the Walter-Lea amendments to the Federal Trade Commission Act and by the Federal Constitution."

Parenthetically, we point out that we disagree with Carter's contention concerning the effect of these amendments.

Our careful examination of the record demonstrates to us that the issue concerning "general informed medical opinion on basic medical issues," was not only a subject of comment appearing in various professional opinions tendered by Carter's expert medical witnesses, but their opinions on this subject were countered by conflicting views expressed by Commission witnesses. From the tenor and purport of testimony offered by Carter's witnesses it is clear that such testimony was introduced to demonstrate the existence or non-existence of a substantial fact, i.e., whether there existed a "consensus of informed medical opinion" which sustained the validity of Carter's advertising claims concerning the many therapeutic virtues of its medicinal preparation.

Carter's position seems to be that this Court should now proceed to weigh all of the evidence on this particular issue and decide just what this evidence had proved, or failed to prove concerning the existence of some sort of a body of "informed medical opinion" as to the therapeutic worth of Carter's product. We disagree. In our view the testimony presented a fact issue which, in any event, would have to be primarily resolved by the Commission in light of all of the expert testimony on the subject. Whatever

might be our personal judgment concerning the probative worth of a huge mass of medical testimony which tended to prove or disprove the existence of such a body of "medical opinion," our views would have to yield to the specialized experience and knowledge of the Commission. The judges of this Court are not equipped by education, training or experience to resolve a factual question of this character which obviously concerns the accuracy of the respective scientific views of men who are practicing the art of medicine. The futility of an attempt by a reviewing court to exercise such a function becomes all the more obvious in face of the fact that medical experts have reached different conclusions on this issue. (See footnote 15, infra.)

PART TWO

The reports contain a host of decisions dealing with the scope of judicial review of orders of federal administrative agencies, and an imposing array of them deal with decisions of the Federal Trade Commission. It is unnecessary to analyze the holdings in many of the apposite decisions[13]

[13] Federal Trade Commission *v.* Pacific States Paper Trade Association, 273 U.S. 52, 63; Corn Products Refining Co. *v.* Federal Trade Commission, 324 U.S. 726, 739; Jacob Siegel Co. *v.* Federal Trade Commission, 327 U.S. 608, 612, 613; American Power & Light Co. *v.* Securities & Exchange Commission, 329 U.S. 90, 103, 106, 115, 116; Reilly *v.* Pinkus, 338 U.S. 269, 274, 276, 277; United States et al. *v.* Storer Broadcasting Co., 351 U.S. 192, 203; Federal Trade Commission *v.* Standard Oil Co., 355 U.S. 396, 400, 401; Federal Trade Commission *v.* Mandel Brothers, Inc., decided May 4, 1959.

American Medicinal Products, Inc. *v.* Federal Trade Commission, 136 F.2d 426, 427; Charles of the Ritz Dist. Corp. *v.* Federal Trade Commission, 143 F.2d 676, 679, 680; J. E. Todd, Inc. *v.* Federal Trade Commission, 145 F.2d 858; Research Laboratories, Inc. *v.* United States, 167 F.2d 410, 415, 416, cert. denied 335 U.S. 843; Willapoint Oysters Inc. *v.* Ewing, 174 F.2d 676, 685, 689, 691, cert. denied 338 U.S. 860; Bristol-Myers Co. *v.* Federal Trade Commission, 185 F.2d 58, 61, 62; P. Lorillard Co. *v.* Federal Trade Commission, 186 F.2d 52; National Labor Relations Board *v.* Howell Chevrolet Co., 204 F.2d 79, 85; Koch et al. *v.* Federal Trade Commission, 206 F.2d 311, 315, 318, 319, 320; Standard Distributors Inc. *v.* Federal Trade Commission, 211 F.2d 7, 12; Dolcin Corp. *v.* Federal Trade Commission, 219 F.2d 742, 749, 751, 754, 755; Tractor Train-

since a comparatively few of them serve to provide a satisfactory answer to the basic review problem confronting us. These few cases have delineated the controlling principles we must apply.

The landmark decision and the one most frequently cited is Universal Camera Corp. *v.* National Labor Relations Board, 340 U.S. 474. In this decision the Supreme Court spelled out with care the general rules that should govern Courts of Appeal in their work of reviewing orders and/or decisions of administrative agencies. The Court held, inter alia, (in conformance with a requirement of the Administrative Procedure Act) that such decisions must be supported by substantial evidence "on the record considered as a whole." If after canvassing and fairly assessing the entire record a reviewing court cannot conscientiously find that the evidence supporting an agency decision is substantial, "good conscience" dictates that the agency decision

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ing Service *v.* Federal Trade Commission, 227 F.2d 420, 425; R. S. Kalwajtys et al. *v.* Federal Trade Commission, 237 F.2d 654, 656, cert. denied 352 U.S. 1025; Jacques DeGorter *v.* Federal Trade Commission, 244 F.2d 270, 273, 281, 283; Abel Allan Goodman, etc. *v.* Federal Trade Commission, 244 F.2d 584, 589, 591, 593, 594, 603, 604; Arrow Metal Products Corp. *v.* Federal Trade Commission, 249 F.2d 83; Loesch *v.* Federal Trade Commission, 257 F.2d 882, 885; G. H. Miller & Co. *v.* United States et al., 260 F.2d 286, 296, 297, 302.

The following cases hold that the Commission has authority to resolve conflicts in expert medical testimony.
Federal Trade Commission *v.* Raladam Co., 283 U.S. 643, 646; Justin Haynes & Co. *v.* Federal Trade Commission, 105 F.2d 988, 989; Dr. W. B. Caldwell, Inc. *v.* Federal Trade Commission, 111 F.2d 889, 891; Neff *v.* Federal Trade Commission, 117 F.2d 495, 497; D.D.D. Corp. *v.* Federal Trade Commission, 125 F.2d 679, 680, 682; John J. Fulton Co. *v.* Federal Trade Commission, 130 F.2d 83, 86, citing cases, cert. denied 317 U.S. 679; Aronberg *v.* Federal Trade Commission, 132 F.2d 165, 170.

It is for the Commission and not the courts to pass upon the credibility of witnesses and/or weight to be accorded their testimony. Tractor Training Service, et al. *v.* Federal Trade Commission, 9 Cir., 227 F.2d 420. Also see Corn Products Refining Co. et al. *v.* Federal Trade Commission, 324 U.S. 726; Federal Trade Commission *v.* Standard Education Society et al., 302 U.S. 112; Standard Distributors, Inc. et al. *v.* Federal Trade Commission, supra, P. Lorillard Co. *v.* Federal Trade Commission, supra.

be reversed. In so appraising the whole record the reviewing court must take into account whatever in the record fairly detracts from the weight of the evidence which underlies the agency order and is "opposed to the agency's view."

The Court also indicated that an order of an administrative agency should be set aside unless justified "by a fair estimate of the worth of the testimony of witnesses *or its* [the agency's] informed judgment on matters within its special competence *or* both"; but the Court also emphasized that the requirement for "canvassing the whole record" in order to ascertain substantiality, *was not "intended to negative* the function of the [there Labor] Board as one of those agencies presumably equipped or informed by experience to deal with a specialized field of knowledge, whose findings within that field carry the authority of an expertness which courts do not possess and therefore must respect." (Emphasis supplied.)

In an opinion issued on the same day, the Supreme Court applied one of the principles announced in Universal Camera. National Labor Relations Board *v.* Pittsburg Steamship Co., 340 U.S. 498. It again emphasized the fact that Congress had charged the Courts of Appeal, and not the Supreme Court, with the normal and primary responsibility for granting or denying enforcement of Labor Board orders. It held that decisions of the Courts of Appeal would not be disturbed when they involve solely a fair assessment of a record on the issue of unsubstantiality; that the Supreme Court is not the place to review a conflict of evidence nor to reverse a Court of Appeals even if the Supreme Court (in the place of the Court of Appeals) would find the record tilting one way rather than the other, and even though fair-minded judges could find it tilting either way. The Court indicated its adherence to the rule that where conclusions of Courts of Appeal "depend on appreciation of circumstances which admit of different

interpretations," the decision of that intermediate court should not be disturbed.

In Federal Trade Commission *v.* Standard Education Society, 302 U.S. 112, the Court considered "unfair practices" related to the methods of sale of certain kinds of books. In passing upon the judicial function of a reviewing court the Court stated: "The courts do not have a right to ignore the plain mandate of the statute which makes the findings of the Commission conclusive as to the facts if supported by testimony. The courts cannot pick and choose bits of evidence to make findings of fact contrary to the findings of the Commission. The record in this case is filled with the evidence of witnesses under oath which support the Commission's findings."

In Federal Trade Commission *v.* Algoma Lumber Co., 291 U.S. 67, the Court again dealt with the findings of the Federal Trade Commission. In reversing a decision of this Court (Algoma Lumber Co. *v.* Federal Trade Commission, 64 F.2d 618) the Supreme Court quoted the Act here involved which provides: "The findings of the Commission as to facts, if supported by testimony, shall be conclusive." 15 U.S.C. Sec. 45. It then went on to hold that "the Court of Appeals, though professing adherence to this mandate, honored it, we think, with lip service only. In form the court determined that the findings of unfair competition had no support whatever. In fact, what the court did was to make its own appraisal of the testimony, picking and choosing for itself among uncertain and conflicting inferences. Statute and decision [citing Federal Trade Commission *v.* Pacific States Paper Trade Assn., 273 U.S. 52, 61, 63] forbid that exercise of power."

The Court concluded with a further holding that "the finding of unfair competition being supported by the testimony, the Commission did not abuse its discretion in reaching the conclusion that no change of the name short of the

excision of the word 'white' would give adequate protection."

Applicability of the principles announced in the Standard Education Society and Algoma decisions, supra, to the problem of review confronting us in the instant case, is clearly demonstrated by the recent reversal of a decision of this Court reported in James H. Sewell *v.* Federal Trade Commission, 240 F.2d 228. The Supreme Court reversed this decision in a per curiam opinion in which we were directed to "affirm and enforce the order of the Federal Trade Commission" on authority of the two Supreme Court decisions just above cited. See 353 U.S. 969.

The judge of this Court who dissented in our Sewell opinion expressed the view that this Court's decision had "meddled in a decision which it is not authorized to make" and he predicated this conclusion on the holdings of the Supreme Court in the Algoma and Standard Education Society cases. The Supreme Court agreed with him.

A late decision of the Supreme Court directly touching the authority of the Commission to formulate orders designed to effectuate the conclusions it has reached, is Federal Trade Commission *v.* National Lead Co., 352 U.S. 419, 429. In that case the Court cited an earlier case wherein it pointed out that "Congress had placed the primary responsibility for fashioning orders upon the Commission" —that the cases have served to narrow the issue to the question: "Does the remedy selected have a 'reasonable relation to the unlawful practices found to exist'." In this connection also see Federal Trade Comm. *v.* Mandel Brothers, Inc., U.S. ————, May 4, 1959.

The Commission is deemed to have expert experience in dealing with matters of the character involved in the instant case. Federal Trade Commission *v.* R. F. Keppel & Bros. (1934) 291 U.S. 304, 314. And it may draw upon its own experience in order to determine (even) in the

absence of consumer testimony, the natural and probable result of the use of advertising expressions. E. F. Drew & Co. *v.* Federal Trade Commission (1956) 2 Cir., 235 F.2d 735, 741. See footnote 60 in De Gorter *v.* Federal Trade Commission, 9 Cir., 244 F.2d 270, 283.

In the Keppel case, supra, the court also took occasion to emphasize that the Commission "was created with the avowed purpose of lodging the administrative functions committed to it in "a body specially competent to deal with them [practices or methods of competition] by reason of information, experience and careful study of the business and economic conditions of the industry affected, and it was organized in such a manner, with respect to the length and expiration of the terms of office of its members, as would give to them an opportunity to acquire the expertness in dealing with these special questions concerning industry that comes from experience."

In the margin[13] we cite a group of cases presenting typical examples of how federal courts have applied and elaborated upon vital phases of the problem which confronts us in the case at bar. We think that these decisions are in harmony with the basic principles laid down in the several decisions of the Supreme Court just above cited in this part of our opinion. In many instances these decisions dealt with challenges to the scope of authority of the Commission to make the particular findings involved which concerned facts in evidence, and/or to fashion a remedy or remedies which under all of the evidence would best afford a just and rational solution for the evils revealed by the evidence.

Part Three

The conclusions expressed below are intended as a supplement to what we have previously said concerning

the several issues of law and fact presented in this long-drawn-out controversy.[14]

The many years consumed in this litigation, the claim of Carter that the Commission's Order will have ruinous effects on its business, the highly involved nature of the lengthy expert medical testimony in the record, plus the vigorous arguments of counsel covering practically all of the material issues of fact along with controversies over procedural points, have provided an added incentive to a scrutiny of the entire record with that degree of care suggested by the Supreme Court. Our scrutiny included a reading of the oral arguments of counsel before the Commission just prior to submission of the case (1956) to the Commission for its final decision on the merits.

In our appraisal and assessment of the record as a whole, we endeavored to make a fair estimate of the worth of the medical testimony of the expert witnesses, having in mind that in the last analysis, the evaluation of the Commission as to the weight to be given such testimony concerning medical truths was a matter committed for decision to the informed judgment of the Commission, and that making a primary decision on that question was a duty that fell within the area of its competence. So far as concerns any *conflicts* in such testimony, we are also of the view that all such conflicts presented questions of fact for resolution by the Commission and not for resolution by this Court. See Irwin *v.* Federal Trade Commission, 143 Fed. 2d 316, 323, and note 13, supra.

Our assessment and estimate of the probative weight of the entire body of evidence also took into account the con-

[14] On the day the Hearing Examiner announced that the record was (then) being closed in the last series of hearings, he stated to counsel that the hearing then being concluded was the "149th hearing" in this long case; that "on the basis of a five day week, that is approximately three and a half months of actual, continuous hearings."

tradictory evidence offered by Carter from which conflicting inferences could be drawn which detract from the weight of the evidence supporting the Commission's view.

The meaning of, and the truth or lack of truth in the florid advertising representations of Carter concerning the therapeutic worth of its pills,[15] *and also* the tendency or capacity of its elaborate advertising to mislead and/or deceive the using public, presented questions of fact to be determined by the Commission under all of the evidence (See Kalwajtys, et al., *v.* Federal Trade Commission (7 Cir.), 237 F.2d 654, 656.) Its conclusions on this phase of

[15] Carter suggests that the Commission was here dealing with a case which involves "harmless therapeutic claims honestly made." It contends that at the time the Commission made its (1956) Order the record then before the Commission failed to reveal that there was a "general agreement of medical opinion" concerning the "falsity of the claim"; that for this reason we should reverse the Commission's Order under authority of the holding in Belmont Laboratories *v.* Federal Trade Commission, 103 F.2d 538, 543, 7 Cir. 1939. As we view this argument, it at least carries the suggestion that the Commission's Order should not be sustained by this court **if any conflict whatever** appears in the medical testimony of the expert witnesses concerning the truth or falsity of the various therapeutic claims appearing in Carter's advertising.

We cannot agree with the foregoing argument. The basic purpose of the entire proceeding was to inquire into the factual truth or falsity of many elaborate "therapeutic claims," employed in Carter's advertising. Whether these many "therapeutic claims" were true or false could only be demonstrated through the testimony of medical experts, and that course was followed. The record shows that when the proceedings ground to a close the parties were apparently in agreement that the dominating and controlling area of factual conflict in this case was what influence, if any, Carter's pills would have on the production and flow of liver bile. Carter claimed that the record then before the Commission demonstrated that its pills would produce that result. Its advertising in evidence had claimed that use of its pills would stimulate an increase in the production and flow of liver bile and thereby produce the many beneficial therapeutic results described in this lavish advertising. On the entire body of evidence and testimony the Commission finally decided that the several therapeutic claims of Carter which were carefully noted in its Order did constitute false and misleading advertising, and as such were unfair and deceptive acts and practices in commerce. We find no rational reason for disturbing the Commission's judgment on this point all as reflected in its Order.

the case must be upheld by a reviewing court unless it can be said that the Commission's rulings on such questions were arbitrary or clearly wrong. Our conclusion is that the rulings here referred to are not to be condemned. The Commission did not err in making and entering its ultimate findings of fact which reflect its conclusions on these matters.

To an overwhelming degree the expert testimony in this case dealt with highly complicated questions of fact, answers to which had to be found in the realm of medical knowledge. We are fully persuaded that this Court is without authority to substitute its judicial judgment on purely medical facts for that of the Commission by weighing the probative force and effect of a body of testimony dealing directly and exclusively with the effect of a certain combination of drugs on the human system. The function of weighing the rational probative force of such testimony was a primary duty imposed upon the Commission. Our assessment of the evidence and testimony leads to the conclusion that the order of the Commission was not clearly wrong nor was it arbitrary.

In argument supporting its claims of error Carter asserts that the Commission's own Findings and Opinion *demonstrate on their face* fatal defects of proof; that taken in light of the record as a whole, they demonstrate beyond peradventure of a doubt that there was *a complete abdication* by the Commission of its duty to weigh the proof in the record which fairly detracted from the weight of its own proof. It is urged that this abdication was due either to the Commission's complete disregard of evidence received or its exclusion of evidence offered by Carter.

It is also argued that every line of the Commission's Decision reflects "the unmistakable badges of a corrosive bias, of refusal even to explore (must less to rectify) the deficiencies of proof and procedure recommitted to it by

this Court and a consistent demonstration of sheer abdication of its duty to weigh or consider the evidence."

We disagree with the contentions set forth in the two preceding paragraphs and we reject them as without real substance or merit.

We also find no merit in Carter's claim of error based on the Commission's action in refusing to disqualify the Hearing Examiner and to terminate the proceedings. Furthermore, the reasons assigned to support Carter's general claims of unfairness (including a denial of its demand to introduce additional evidence and for a de novo hearing before a different examiner on all of the issues in this litigation) do not appeal to us as possessing that degree of substance and real worth which would justify a reversal of the Commission's Order and possibly result in an indefinite continuation of this controversy. In this connection, we are also persuaded that the record, as a whole, fails to show that in this proceeding the actions of the Hearing Examiner and the Commission shifted the burden of proof to Carter. A contention to that effect is without merit.

Viewing the record in its entirety, we find no sound reason which, in good conscience, would justify us in impeaching the substantiality, the evidentiary worth, force and persuasiveness, of the body of evidence which the Commission ultimately relied upon to support its Findings of Fact Nos. 3, 4, 18 and 20 to which we made specific reference earlier in this opinion. As we read the record it is plain that much that appears in these four findings is but a recapitulation or restatement of portions of the totality of facts as found by the Commission in some of its other findings. So far as concerns the factor of "substantiality," our considered judgment is that the body of evidence which sustains the four findings here mentioned was substantial and that this evidence provides adequate support for the Order here on review.

Even the most casual inspection and appraisal of the entire record would reveal that in all material phases of the long controversy between the parties to this proceeding, the dominating fact issue stressed in the testimony of the expert medical witnesses was whether use of Carter's laxative pills would, or would not, have any influence in stimulating an increase in the *production* of bile by the liver and would or would not, increase the *flow* of liver bile. (See footnote 7, supra.) From all of the evidence, the Commission found as a fact that this particular claim which Carter characterizes as its "basic therapeutic claim" was false and misleading; that use of Carter's pills would have no effect whatever on functions of the liver, and would not cause the liver to produce *an increased flow* of bile nor would it have any influence in the *production* of bile by the liver. On this factual basis which directly concerned the therapeutic value of Carter's pills, the Commission Order also enjoins the further use of the word "liver" in the trade name of "Carter's Little Liver Pills." We think the Commission was acting well within the orbit of its authority when it ordered excision of the word "liver" from the trade name of Carter's product.

And we point out that despite Carter's sweeping claim in its brief that its business will be totally destroyed if the Commission's Order is sustained, the Order *does not* enjoin Carter from use of advertising claims concerning the *cathartic* properties of its pills *unless* such claims are of a character clearly prohibited by the express terms of the Commission's Order.

The Commission concluded (in its Order) that "the acts and practices of the respondent, as herein found, are all to the prejudice and injury of the public and constitute unfair and deceptive acts and practices in commerce within the intent and meaning of the Federal Trade Commission Act." We agree with this conclusion. Furthermore, we think that

the Commission made an allowable judgment in its choice of a remedy to be applied. The Commission is the expert body to determine *what remedy* is necessary to eliminate the unfair and deceptive practices disclosed by the record, and it has wide latitude for judgment. Shaping a remedy is essentially an administrative function. Congress has entrusted the Commission with the responsibility of selecting *the means* of achieving a statutory policy—the relation of remedy to policy is peculiarly a matter for administrative competence. Here, the Commission had discretion to fashion a remedy of a civil nature to attain the desired goals, and its choice fell within an allowable area of its discretion. Only in cases where the remedy selected has no reasonable relation to the unlawful practices found to exist, should a reviewing court interfere. We are convinced that this is a case where an interference by this Court with the breadth of the Commission's Order would clearly lack justification.

The Act prescribes that the findings of the Commission as to the facts, if supported by evidence, shall be conclusive on a reviewing court. 15 U.S.C.A. Sec. 45(c). The Administrative Procedure Act added the further requirement that to be valid, the findings of federal administrative agencies must be supported by *substantial* evidence in the record considered as a whole. The record meets this test.

Carter urges in its brief that this case is unique in the annals of Federal Trade Commission proceedings; that in view of the great age of the litigation, the end issue which involves purely questions of "general medical opinion," and particularly in view of "the changing nature of these specific medical frontiers"—where the criteria for establishing the truth or falsity of a therapeutic opinion are peculiarly in constant flux, this court should not only refuse to approve the Commission's Order but should remand the case to the Commission with directions to take additional

evidence *which would show* that the entry and enforcement of the Commission's 1956 Order "is appropriate under present circumstances"—which evidence would also "reflect the present day status of these controversial medical topics."

Our answer to the foregoing claim is that the Commission was the body to decide whether, (in 1956) the totality of evidence then in the record refuted the "therapeutic opinions" advanced by Carter in its profuse advertising claims and supported in the testimony of its witnesses. While Carter had pleaded in its Answer, that it had abandoned the use of some of the advertising claims referred to in the Commission's Complaint, nonetheless in this same pleading it also frankly avowed that "the advertising of Carter's Little Liver Pills truthfully describe its properties." Its brief also urges that *its* convincing presentation of the merits of its case, and *its* analysis of *its evidence and its experiments*, should impel us to conclude that such a showing resulted in "fully establishing the truth of its therapeutic claims."

In argument to this Court the Commission's brief urges that except as to the representations that Carter's laxative will effect the production or flow of bile, Carter's counsel made little or no effort to establish the truth of the many other representations made in Carter's advertising as to the therapeutic value of its laxative pill. (See footnote 7.)

It is our considered judgment that the instant Order of the Commission requiring Carter to cease and desist from further disseminating certain specified false and misleading claims concerning the therapeutic virtues of its pills, presents the only barrier to a possible renewed use of many or all of such therapeutic claims in any future advertising by Carter. On the whole record we would not be justified in substituting our judgment for that of the Commission in

shaping the remedial provisions of its Order. The Commission urges in its briefs that there is *no evidence in the record* which would show that Carter had discontinued the various advertising statements found to be false and misleading, and which statements furnish the basis for the Commission's Order to cease and desist. In view of this situation and under all of the circumstances of this case we conclude, and therefore hold, that the Commission did not abuse its discretion in issuing this Order. See Marlene's Inc. et al., *v.* Federal Trade Commission, 216 F.2d 556, 559, 560.

The petition of Carter to reverse and set aside the Cease and Desist Order of the Commission is denied. The said Order is affirmed, and obedience to its terms is hereby Ordered.

(Endorsed:) Opinion. Filed June 16, 1959.

PAUL P. O'BRIEN, Clerk.

(2)

Opinion of The Federal Trade Commission Filed October 4, 1956.

UNITED STATES OF AMERICA

BEFORE FEDERAL TRADE COMMISSION

Commissioners: JOHN W. GWYNNE, Chairman,
LOWELL B. MASON,
ROBERT T. SECREST,
SIGURD ANDERSON,
WILLIAM C. KERN.

[Title of Cause.]

OPINION OF THE COMMISSION

By KERN, Commissioner:

The issues in this proceeding relate to whether the advertising disseminated by the respondent for the product designated "Carter's Little Liver Pills" has constituted false advertisements within the meaning of the Federal Trade Commission Act.

After the United States Court of Appeals for the Ninth Circuit granted the petition of Carter Products, Inc., to review and set aside the Commission's order and subsequently remanded this matter to the Commission with authority to reopen it for further evidence, the Commission issued its order reopening the proceeding. Additional hearings were convened at which the respondent further cross-examined two scientific witnesses called in support of the charges of the complaint at the original hearings. On motion by the respondent, all evidence relating to certain medical experiments introduced through another witness whose career was closed by death was stricken by the hearing examiner. The Commission having considered the record as presently constituted, including the evidence additionally received at the supplemental

hearings, has made its modified findings as to the facts and reached determinations that certain of the practices of the respo. lent, Carter Products, Inc., as therein designated have been in violation of the Federal Trade Commission Act. Our decision contains an appropriate order. While those findings include statements of reasons controlling to the Commission's decision on the merits of the charges, supplemental discussion of certain of them and matters of law especially emphasized by the respondent in its briefs is deemed warranted.

The respondent's position that the charges of the complaint have inadequate record support rests in part on its contentions of alleged defects and undue limitations inherent in the procedures adopted in the scientific experiments introduced in support of the charges of the complaint. The hearing examiner's rulings in receiving that evidence initially and in denying the respondent's subsequently interposed motions to strike certain of that evidence have sound legal basis. The Commission's findings as to the facts include statements of reasons why exceptions to the reliability of certain of those test procedures are not well taken and why the results of the animal experiments are transferable to human beings. Save for the experiments which utilized the less conclusive duodenal drainage method, we think that their results are material to the issues here and there can be no doubt that they, in the aggregate, constitute a very impressive and persuasive body of scientific evidence.

In urging that its evidence concerning experiments which utilized duodenal drainage methods outweighs other evidence received, the respondent maintains that this drainage procedure is a generally accepted and accurate scientific method. The Commission's findings as to the facts contain a discussion of various record matters which detract from the reliability of the scientific experiments introduced by the respondent and which render those studies inconclusive. While duodenal drainages are apparently a reliable

basis for many diagnostic determinations, the fact remains that the comparative results of a relatively small number of such drainages do not constitute authoritative determinations as to the relative capacity of an individual's biliary system at different times. As also noted in the Commission's findings as to the facts, this is partly due to the circumstances that the rate of bile flow is subject to great variations in the same person.

One of the various exhibits pertaining to experiments relied upon by the respondent in support of claims for product efficacy includes comparisons of the averages of biliary values for drainages made for nine subjects following a stimulant to bile flow but without medication with those afforded by the same stimulant but after medication with Carter's Little Liver Pills. It was conceded that 7 of the 9 subjects yielded one or more drainages during control periods, with or without the stimulant but without medication by the pills, in which bile constituents were as high as or higher than others with like stimulation plus medication. This manifestly tends to detract from the conclusiveness of the experimental results; and further illustrating the highly variable nature of bile flow is the fact that one subject's values for bile acids during his 3 control drainages which were listed in the exhibit were reported as 128, 1783, and 432, while his 2 drainages with medication showed values of 2458 and 953. For another subject in the group, those values in the absence of medication represented 59, 284, and 1028, and with medication were 397 and 1600.

The respondent also argues in effect that the conflicts of medical opinion presented in the record preclude informed determinations that its product does not influence bile flow and reflect a scientific controversy requiring this proceeding's dismissal. It is true that the results of experiments reported in the scientific literature dealing with effects exerted by aloes and podophyllum have presented some conflict. However, the scientific studies received in support

of the charges of the complaint relate in the aggregate to a wide range of experimental conditions and constitute highly probative evidence as to the limitations of the respondent's preparation.

The circumstances, among others, emphasized by the respondent, that biliary disturbances and constipation may occur contemporaneously in an individual, that a complete absence of bile in the intestine is a predisposing factor to constipation, and that a possibility of a connection between some function of the liver and physiological processes resulting in constipation exists, do not reach to the core of the scientific issues. It is controlling, on the other hand, that there is no known disease of the liver or biliary system which is beneficially affected by the ingredients of the respondent's preparation. There is no authoritative scientific evidence that constipation could decrease the secretion of bile by the liver to such an extent that there would be insufficient bile in the system to carry on the function of that fluid. Furthermore, the greater weight of the evidence establishes, among other things, that these drugs are not specific stimulants either to the flow of bile or its formation. Although the respondent offered some evidence to the contrary, the record contains other clear and convincing evidence that laxation does not reflexly increase bile flow and, conversely, that constipation or poor intestinal mobility does not act physiologically to reduce the formation or flow of bile. Having considered the conflicts in the evidence, we think that the record supports informed determinations that the respondent's preparation is devoid of any beneficial influence on the formation of flow of that body fluid.

At the close of the supplemental hearings, the respondent filed certain motions to strike evidence previously received and other motions or offers of proof, together with affidavits in support of the latter. One of the motions requested the hearing officer to strike all the X-Ray studies

introduced through Dr. Case and all testimony pertaining in any way thereto. At the original hearings held in 1943, prints of films relating to 7 of 25 participants were received in evidence subject to subsequent motion by the respondent to strike, and the originals thereof later were received. While the conclusiveness of the testimony and documentary evidence presented through Dr. Case was challenged when the case was heard originally by the Commission, the propriety of their reception in evidence does not appear to have been raised until the hearings on remand were being held in 1954. Included in the errors assigned under the motion was that the radiologists who made the films were not called; that patients' medical records were not made available for counsel's use; and that not all the films for any one of the 25 participants were produced.

It appears, however, that during the original hearings an offer was made to the respondent to produce additional films relating to the 7 subjects to which the exhibits related and others as well. In view of the particular experimental design adopted furthermore, it is immaterial that medical data for the subjects were not produced for inspection. Reverting now to the error alleged incident to failure to produce the radiologists responsible for the pictures, the record shows that minutest details in posing the subjects and setting the button received Dr. Case's attention in the studies for 3 of the subjects to whom the exhibits relate. The films for the other 4 were made in a departmental clinic which was under his supervision and by technicians trained in the procedures effective there for making X-Rays of this type.

Although sanctions are not to be imposed unless supported by reliable, probative and substantial evidence, the Administrative Procedure Act states that any oral or documentary evidence may be received. Some of the evidence introduced through Dr. Case clearly was based on his personal participation in the experiments he had devised.

Evidence resting in part on the personal observation of a witness and in part on hearsay is manifestly competent and unobjectionable insofar as it rests on the personal observation of the witness. U.S. *vs.* Aluminum Co. of America, 35 F. Supp. 820, 822 (S.D. N.Y. 1940). Not only did the witness deem the films to be reliable and trustworthy bases for the opinions expressed by him, but they represented professional services performed for clinical patients. Hence, there can be no doubt but that this evidence is of the kind "on which responsible persons are accustomed to rely in serious affairs." N.L.R.B. *v.* Remington Rand, Inc., 94 F. 2d 862, 873 (C.A. 2, 1938).

Having reviewed all the matters urged by the respondent on this aspect, we are convinced that it was proper for the hearing examiner to deny its request to strike. We also have considered the motion which requested the hearing examiner to strike all evidence relating to Dr. Bollman's experiments. The matters relied on in support of that motion essentially pertained to evidentiary weight and its denial likewise was fully warranted.

Proceeding on to consideration of the adverse rulings on the motions or offers of proof, the categories of proof which the respondent requested the hearing examiner's leave to introduce included (a) the evidence of a scientific witness, Dr. John R. Twiss, and a statistician witness in corroboration of evidence submitted by the respondent during the original hearings; (b) other evidence by that scientific witness to refute evidence presented through Dr. Bollman and Dr. Case, who were called in support charges of the complaint; (c) data relating to new experiments conducted by Dr. Twiss, which assertedly show that Carter's Little Liver Pills have a significant effect on flow and formation of bile; and (d) certain medical texts or treatises including those marked for identification during the course of Dr. Bollman's cross-examination in the supplemental hearings.

The procedural situation which existed when the respondent filed its motions was that the supplemental hearings had drawn to a close. These supplemental hearings had been held pursuant to the Commission's order of December 18, 1953, under which the case was remanded to the hearing examiner "for such further proceedings as may be necessary to correct the errors in the original hearings specified by the Court of Appeals." The errors referred to in that order were those pointed out by the Court of Appeals for the Ninth Circuit in its opinion rendered January 19, 1953 (Carter Products, Inc. *v.* Federal Trade Commission, 201 F. 2d 446); and the remand to the hearing examiner was made pursuant to authority granted by the Court in its mandate of November 18, 1953, whereby the Commission was authorized "to open the proceeding for further evidence and a new order consistent with the opinion of this court."

In its opinion of January 19, 1953, the Court had stated:

"Questions pertaining to the sufficiency of the evidence or to the merits are not presented by the petition. What is claimed, principally, is that a fair hearing was denied petitioner in that the trial examiner unduly and prejudicially restricted its right of cross-examining certain of the Commission's expert witnesses upon whose testimony, in large measure, the findings and order were based. The witnesses in question were Doctors Carlson, Bollman, Lockwood and Case. We are of the opinion that petitioner's claim is well grounded in respect of the three experts last named, but not in respect of the witness Carlson."

And, after pointing out the rulings wherein the errors were made, the Court ended its opinion as follows:

"It is argued that there was ample evidence from other quarters to sustain the findings and order of the Commission, hence the rulings, even if wrong, were not prejudicial. We are of opinion, however, that the cumulative effect of these unjustifiable restrictions on the cross-examination of

key witnesses for the Commission was to deprive petitioner of a fair hearing. Such being the case the court is not disposed to speculate as to what would have been the outcome had a fair and impartial hearing been accorded. (Citing authorities.)

"The order of the Commission is set aside."

It seems obvious to us, therefore, that the reason for the Court's action setting aside the Commission's order to cease and desist was that the respondent had been denied a fair hearing before the Commission in that the hearing examiner unduly and prejudicially restricted the respondent's right to cross-examine Doctors Bollman, Lockwood and Case. It seems equally obvious that the purpose and effect of the remand was to enable the Commission to correct the errors in this respect by recalling these witnesses for full cross-examination. This the Commission had undertaken in good faith to do. At a hearing held in Santa Barbara, California, Dr. Case had been recalled to the stand and tendered to the respondent for further cross-examination. After 130 pages of testimony had been received, the respondent's counsel had announced "I have asked all the questions I want to ask." (R. 10,838) At a subsequent hearing held in Washington, D. C., Dr. Bollman had been recalled to the stand and thereafter further cross-examined. After 268 pages of testimony had been received, the respondent's counsel had again announced "I have no [further] questions." (R. 11,193) Dr. Lockwood, the third witness whose cross-examination the Court held had been improperly curtailed had, in the meantime, died. In view of his unavailability for further cross-examination, all of his testimony and all exhibits theretofore offered in support thereof had been, on the respondent's motion, stricken from the record. Thus, the purpose and intent of the remand had been fully served. The additional matters proffered by the respondent essentially constituted cumulative evidence similar in vein to that introduced by the

respondent at the original hearings. They were in no sense within the purview of the Court's remand to the Commission or the Commission's remand to the hearing examiner, neither of which contemplated use of the supplemental hearings for retrial of the issues and matters as to which full hearing or opportunity therefor had been afforded in the original hearings, and the hearing examiner's action in rejecting this additional evidence is not regarded as erroneous.

Counsel supporting the complaint has stated that he would not oppose a proper motion filed by the respondent requesting the reception of evidence relating to Dr. Twiss' experiments as newly discovered evidence. In presenting its arguments to the Commission on the merits, the respondent averred that such evidence is material and was unavailable to it at the time of the original hearings; but the respondent likewise then indicated clearly that it does not now desire the reception of such evidence by the hearing examiner. The respondent instead urges that a choice of two courses of action is now incumbent on the Commission, namely, hearings de novo before another hearing officer because of alleged bias and prejudice by the present hearing examiner, or dismissal of this proceeding for failure of proof. The Commission having determined that the respondent's motion to disqualify the hearing examiner was not well taken, we must reject the respondent's contention that it is entitled to a trial de novo. The respondent having elected not to pursue the matter further by filing for our consideration a proper motion and having an evident intent to rely on the rulings below as constituting prejudicial error invalidating all prior proceedings herein, it was appropriate that the Commission proceed to a consideration of the case on its merits. This the Commission has done and its decision, representing the result of its own exhaustive examination of the record, is issuing herewith.

Our consideration of the arguments advanced by the respondent in support of its request for dismissal has

included those presented under its original exceptions as well as others urged for the first time after the supplemental hearings. Their separate discussion and individual rulings in respect thereto would unduly lengthen this opinion and, to the extent that they are in conflict with our decision herein, such exceptions and objections are denied.

Commissioner Mason did not participate in the decision herein.

October 4, 1956.

(3)

Opinion of the Ninth Circuit Court of Appeals On Former Appeal, Filed January 19, 1953.

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

CARTER PRODUCTS, INC.,
Petitioner,
vs.
FEDERAL TRADE COMMISSION,
Respondent.

No. 12,940
Jan. 19, 1953

Petition to Review and Set Aside Order of the Federal Trade Commission

WILLIAM L. HANAWAY

STODDARD B. COLBY, *et al.* for Carter Products, Inc.

W. T. KELLEY

ROBERT B. DAWKINS, *et al.* for the Federal Trade Commission

Before: HEALY, BONE, and ORR, Circuit Judges.

HEALY, Circuit Judge.

This case is before the court on petition to review and set aside an order of the Federal Trade Commission pertaining to a product labeled "Carter's Little Liver Pills, A Laxative aiding bile flow."

In summary, the Commission found that the product does not stimulate the liver, aid the flow of bile, or have a therapeutic value in the treatment of any condition or disorder of the liver. The order does not prohibit the contin-

ued sale and distribution of the pills as a laxative, but does require the producer to cease and desist from all advertising claims relative to their therapeutic action on the liver or the flow of the bile, and it directs the excision of the word "Liver" from the trade name.

Questions pertaining to the sufficiency of the evidence or to the merits are not presented by the petition. What is claimed, principally, is that a fair hearing was denied petitioner in that the trial examiner unduly and prejudicially restricted its right of cross-examining certain of the Commission's expert witnesses upon whose testimony, in large measure, the findings and order were based.[1] The witnesses in question were Doctors Carlson, Bollman, Lockwood, and Case. We are of opinion that petitioner's claim is well grounded in respect of the three experts last named, but not in respect of the witness Carlson.

1. Dr. Carlson, a specialist in physiology, testified that Carter's pills, the ingredients of which are aloes and podophyllum, have no known therapeutic action over and beyond their laxative properties, and none upon the liver. He professed himself as being "pretty familiar" with the literature on the subject of the liver and the gastro-intestinal tract, and said that it is the consensus of informed medical opinion that aloes and podophyllum are capable of no action on the functioning of the liver. On cross-examination he was asked whether he knew a Dr. Alvarez of the Mayo foundation and whether he was familiar with the latter's book entitled "Nervousness, Indigestion and Pain," and he replied that he knew Alvarez and had read his book. He said Alvarez "is pretty well informed, but that does not mean that I regard him as sound on all points. I have differed

[1] Petitioner also urges that fatal error was committed in admitting evidence pertaining to certain experiments on dogs and human patients. In our opinion the objection to these experiments, several of which will be mentioned hereafter, goes to their weight only, not to their admissibility.

with him on many things, particularly on motility of the gastro-intestinal tract." He added that in formulating his views he had not relied on the works of Dr. Alvarez. Counsel for the petitioner then proposed to read to the witness an excerpt from the book and to question him concerning the same. The trial examiner sustained an objection and ruled that in order to permit the reading of excerpts from a treatise into the record on cross-examination it must first be shown that the witness had predicated his testimony in whole or in part upon the particular book or the particular author.

Later on, counsel questioned the witness concerning a medical dictionary that apparently had the blessing of the American Medical Association, or at any rate of Dr. Fishbein, and offered to read from it. As regards this book Carlson said it was authoritative as a dictionary but not as a scientific work. The examiner sustained an objection to the reading on the same ground as before.

These are the only specific offers of this nature we have been able to find in the record in connection with the cross-examination of Carlson. A study of his testimony on direct shows that the opinions he expressed were based on his own knowledge and experience and on treatises of medical men, particularly those in the field of internal medicine, whom he regarded as informed on the subject. We are not prepared to hold that the rulings of the examiner in these instances amounted to an abuse of discretion. The general view is that medical treatises are not in themselves competent evidence, since they constitute statements made out of court by persons not available for cross-examination. A conflict of authority exists as to the use that may be made of them in the cross-examination of experts, many courts holding that they may not be used unless the witness on direct has based his opinions wholly or in part on a particular author, in which case the authority may of course be used for the

purpose of contradicting or discrediting the witness.[2] Here, unlike the situation in Reilly *v.* Pinkus, 338 U. S. 269, no issue of fraudulent intent was involved.

Turning, however, to the cross-examination of the other experts mentioned, we think the rulings of the examiner tended to be insufferably technical where not wholly erroneous.

2. Dr. Bollman, called by the Commission, was a physiologist and biochemist of note.[3] Among numerous other activities he served as an assistant director of the Mayo experimental research laboratory, organizing and carrying on a program which he said might be covered by the broad term "Experimental Pathology," embracing physiology, biochemistry and pathology. Most of his time had been spent in problems associated with the liver, and he had done considerable work on the gastro-intestinal tract. A bibliography listing 166 of his published articles was introduced in evidence by the Commission.

A witness for the petitioner, Dr. Morrison, had testified to experiments and tests designed to show that the relief of constipation by Carter's Little Liver Pills stimulated the flow of bile. Dr. Bollman undertook to discredit the findings of Morrison by means of an elaborate statistical document or chart which he had prepared and which he said was a method of his own for analyzing and criticizing Dr. Morrison's experiments and data, this document, marked Exhibit 202, being received in evidence over petitioner's objection. On cross-examination relative to this method Bollman said he had used the identical method in analyzing

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[2] For some of the cases pro or con see: Reck *v.* Pacific-Atlantic S.S. Co., 2d Cir., 180 F. 2d 866; Mutual Benefit Health & Accident Ass'n *v.* Francis, 8th Cir., 148 F. 2d 590; Laird *v.* Boston & M.R. Co., 80 N.H. 377, 117 Atl. 591. Contra: Western Union Telegraph Co. *v.* Ammann, 3d Cir., 296 Fed. 453; Drucker *v.* Philadelphia D.P. Co., 35 Del. 437, 166 Atl. 796; Commonwealth *v.* Phelps, 210 Mass. 109, 96 N.E. 69.

Consult also Wigmore on Evidence, 3 Ed., Vol. VI, §1700.

data in some of the scientific papers he had written. His attention was called to one of his articles and he was asked whether he had treated the data in that instance as he did Dr. Morrison's data, and he replied that he had not. For the announced purpose of testing the validity of the method he employed in his criticism of Morrison's data he was asked the following question: "Doctor, there are 166 of your publications listed in Commission's Exhibits 194-A to O and I will hand you that and ask you to point out if you can wherein you used the method represented by Commission's Exhibit 202 for analyzing Morrison's data in any one of your 166 articles?"

The question was objected to by counsel for the Commission, and in support of his interrogation petitioner's counsel stated: "I think since Dr. Bollman has reported on 166 different subject matters in his publications, many of which contain tables and sets of figures which are set forth to portray findings of facts that he made in his experiments, and since he had been called upon by the Commission to analyze the data of one of my former witnesses and has done it in a certain way which he states is the proper way to do it, and since the one and only paper of Dr. Bollman that I have in my possession now has been presented to him and he has testified that he did not use that method, that he used for analyzing Morrison's data in the article, although it contained sets of figures, I want to know where he has used it in any other, and whether he used it solely for analyzing his figures, and data in any of the other 165 articles that he has written."

The trial examiner ruled as follows: "I am going to sustain the objection and put the burden upon you [petitioner's counsel] of proving that the doctor's method is inherently wrong, and I am going to further assume for the purpose of the ruling that this is a novel method that he has developed which to him in his scientific way makes him believe that it is sufficient, and so let the exhibit stand just as it is."

Insisting upon his right to inquire, petitioner's counsel indicated his willingness to take Bollman's "best recollection" of the number of times he had used his method in the past without requiring him to go through the whole list of articles. The examiner, however, declined to change his ruling. It seems to us that counsel was entitled to put the matter into proper perspective by inquiring whether and to what extent the witness' method conformed to standards employed by himself in other similar tests which he had performed. The ruling foreclosed inquiry along this line, and would appear even to have cut off effective cross-examination as to whether the method conformed to accepted technical and scientific standards.

Another instance of undue restriction of the cross-examination of Dr. Bollman will be noticed. This witness had performed a series of tests on dogs, the object of which was to prove that constipation has no effect upon the secretion or flow of bile. The dogs were anesthetized with ether. Their colons were surgically severed and the lower end of the intestine sewed up so as to bring about a complete intestinal obstruction or "obstipation," a condition which the doctor said does not exist in man. With no means of elimination, the dogs were regularly fed on a diet including glucose until in a matter of days they died or were destroyed. All had peritonitis at the time of death. The results of the experiments were ascertained by autopsies after varying degrees of post-mortem degeneration had taken place. The witness said that these examinations showed no impairment of the liver function. He testified broadly on direct that the results of his experiments are translatable to the human being, and deduced therefrom and on the basis of his own knowledge that constipation in man in no way impairs the functioning of the liver, and that "there is no relationship between constipation and the secretion of bile by the liver."

On cross-examination counsel sought among other things to inquire whether, functionally, man and dog react

to the same stimuli in the same manner. A question to this effect was objected to and the examiner ruled: "The objection is sustained, unless counsel will state the particular stimuli referred to, whether it be food, drugs, or medicine." Counsel then undertook to question Bollman with respect to the stimuli of named drugs. The examiner sustained an objection to this line of questioning, saying that he thought the doctor had not "qualified . . . as a pharmacologist, hence I will not permit him to be questioned as to the possible effect of drugs upon the human body and upon that of dogs." Counsel called attention to the witness' testimony that the experiments he had performed on dogs are translatable to man and said, "I should think that it would be perfectly proper for me to develop in what types of situations reactions on dogs cannot be translated to man."

The examiner thereupon switched the ground of his adverse ruling from the absence of qualification in the witness to the nature of the experiments, stating that the experiments had not been performed with the use of drugs or medication, but had been essentially surgical in nature. He added "just let the ruling stand."

As already appears, the witness had been broadly qualified as an expert. His experiments on the dogs had been performed with the use of the drugs bromsulfaelin and ether, and possibly others. Many of the studies he had made and which were included in the 166 publications introduced by the Commission apparently dealt with the effect of various drugs on dogs and other animals, including humans. And he had testified on direct as to the effects of drugs on both man and animals, and had given it as his opinion that experiments with drugs on animals are transferable to man.

We think that questions as to the transferability generally of tests on dogs in connection with the working of the liver, and more specifically as to the extent to which these artificial and seemingly bizarre experiments might

be regarded as simulating normal constipation in man, were proper subjects for scrutiny and justified a reasonably broad range of exploration on cross-examination. The examiner's rulings would thus seem to have foreclosed inquiry into matters bearing materially on the validity of the experiments.

3. Dr. Lockwood, testifying for the Commission, was a specialist in surgical research at the University of Pennsylvania Medical School and had written many scientific treatises. He treated diseases of the liver, hepatic system, gall bladder, and digestive system. In sum, the recitation of his qualifications was truly formidable, consuming approximately seven pages of the record.

He had at the instance of the Commission supervised and participated in tests made in the University medical hospital the purpose of which was to determine whether Carter's Little Liver Pills, administered to patients from whom total collection of bile had been obtained, would influence the production of bile in respect to volume and cholic acid content. His experiments were performed in the surgical ward of the hospital on twelve patients, all of whom were recuperating from major internal operations. Several of the patients had been suffering from jaundice shortly prior to the experiments, and the gall bladders of all but three had been removed before the collection of bile was begun. The tests entailed the insertion of a T-tube through the sphincter of Oddi into the common bile duct leading from the gall bladder and the liver to the duodenum. The T-tube was connected with a bottle system and a pump, permitting the collection in the bottles of the bile passing through the upper portion of the common duct. The quantity of bile collected varied somewhat from day to day throughout the whole course of the experiments, but the witness thought the variations were without significance. During the process of the collection, and a number of days after it began, doses of Carter's pills were given the patients. The witness gave

it as his opinion on the basis of these experiments that the pills in no way influence the output of bile.

On cross-examination counsel for the petitioner undertook to inquire of the witness whether the condition of the experimentees was not abnormal and whether the tube and suction pump inserted in the biliary tract would not hamper the free flow of the bile. He asked whether in a normal individual, without the use of any such apparatus as was employed in the experiments, the common duct and gall bladder and the cystic ducts are not filled with bile most of the time. The witness answered, in effect, that they would be filled or partly so. The examination continued in the manner following:

> "Q. At the lower end of the common duct is a sphincter? A. Yes.
>
> Q. Where the common duct enters the duodenum? A. Yes.
>
> Q. And as the system requires bile, that sphincter opens and closes into the duodenum from time to time, does it not? A. That is right.
>
> Q. And when the sphincter closes, there is a back pressure that is built up? A. Yes.
>
> Q. In the biliary system? A. Yes.
>
> Q. And does that back pressure have any influence at all on the flow of bile from the liver?"

The latter question was objected to as not being within the scope of the direct examination. The examiner ruled that "the Doctor here has not been qualified by the Commission's attorney as an expert on all of these various phases of the liver and the biliary tract. If you [referring to petitioner's counsel] care to undertake to qualify him, that would be a different matter, but it would seem to me that you are going beyond the scope of the direct examination." Another question along the same line was then asked and objected to, counsel for the Commission stating: "Now if Mr. Hanaway wants to qualify the Doctor and use him as

his witness on that, that is up to him." In sustaining the objection the examiner said: "I do not believe Dr. Lockwood has been qualified as an expert on the liver and biliary tract, for which reason I will uphold the objection, and give you an opportunity, if you care to, to qualify the witness on your own behalf, if you can. . . ." The following then occurred:

> "Q. (by Mr. Hanaway) [petitioner's counsel]: Do you understand the operation of the biliary system, Dr. Lockwood?
>
> Mr. Cohn [for the commission]: Well, of course he is making him his witness, your Honor.
>
> Trial Examiner Purcell: I think Mr. Hanaway understands that.
>
> The Witness: I have a sufficient working knowledge of the function of the biliary tract so that I wouldn't hesitate to treat patients for biliary tract disease.
>
> Q. (by Mr. Hanaway): Do you think you know enough about the operation of the biliary system under normal conditions to answer my questions concerning it? A. I can answer any question you have asked me so far, yes.
>
> Mr. Hanaway: May I now proceed with the questioning, Mr. Examiner?
>
> Trial Examiner Purcell: With the understanding that from this point forward, you have made the witness your own."

At this juncture petitioner's counsel disclaimed any purpose of sponsoring the witness, and upon an attempted resumption of the cross-examination the following occurred:

> "Q. [By Mr. Hanaway] There is no mechanism in a normal human being that corresponds to this pump that you have described Commission's Exhibit 148, is there, Doctor?

Mr. Cohn: Objection, your Honor.

Trial Examiner Purcell: Objection sustained.

Q (by Mr. Hanaway) Then so far as the presence of the suction is concerned through the common duct and into the biliary system, that condition was abnormal, was it not?

Mr. Cohn: I object, your Honor.

Trial Examiner Purcell: Objection sustained."

Little comment seems necessary. Dr. Lockwood himself professed his ability to answer the questions asked. As to his qualifications to do so, his experiments necessarily presupposed an extensive knowledge on his part of the biliary system. Throughout more than 150 pages of direct testimony he had been permitted to describe the intricate surgical experiments performed on the biliary systems of these twelve patients, all of whom were in the hospital for treatment of diseases of the gall bladder and biliary tract. Here, too, the abnormal condition of the experimentees plus the artificiality of the means by which the tests were carried on, suggested at least the possibility that the experiments had little if any value as support for the conclusions drawn from them.

More especially in the case of expert witnesses, cross-examination is of necessity exploratory and should be given broad latitude. Neither counsel nor the judge can know in advance what chinks may be disclosed in the armor of the expert or what frailties revealed in his premises. Cf. Alford *v.* United States, 282 U. S. 687. The condition imposed by the examiner that petitioner make this adversary witness his own was flagrant error. As Judge Sanborn remarked in Heard *v.* United States, 8 Cir., 255 Fed. 829, 832, "[i]t is no answer to a refusal to permit a full cross-examination that the party against whom the witness is called might have made him his own witness, and might then have proved by him or by some other witness, or by some writing, the

facts which the cross-examiner was entitled to draw from the testimony of his adversary's witness. No one is bound to make his adversary's witness his own to prove facts which he is lawfully entitled to establish by the cross-examination of that witness. The testimony given by a witness on his cross-examination is the evidence of the party in whose behalf he is called and the cross-examiner has the right to bind his adversary by the truth elicited from his own witness."

4. Dr. Case, a Commission witness, testified at length on direct concerning his qualifications. He specialized in radiology, had several degrees, and was a fellow or member of numerous learned bodies including the American and French Societies of Gastroenterology. He had written a four-volume Atlas and text on the digestive tube, and had contributed chapters to various medical books on a variety of subjects. Asked especially what studies and work he had had in gastroenterology, he replied: "All my life I have been especially interested in gastroenterology, and have done a great deal of gastroenterological surgery. I have always been interested in it. My X-ray work, if I have any special interest, has been in the digestive tube, especially gall bladder, stomach and bowel." He had, he said, performed over a thousand gall bladder operations and thought it would be fair to say that he had done about 15,000 tests of the gall bladder by a method of visualizing that organ.

On behalf of the Commission the Doctor undertook an assignment described in the trial examiner's report as the making of "certain experiments with Carter's Little Liver Pills to ascertain what effect said pills had upon the functioning of the liver in the production of bile, and of the gall bladder in the flow, storage, and concentration of bile."

For these experiments the witness had used a number of subjects to whom he administered a dye which would make the gall bladder and certain other parts of the biliary

system visible when X-rayed. The subject was then required to eat a carbohydrate meal, all fats and proteins being eliminated. Following this an X-ray picture was taken of the gall bladder, and immediately the subject was given Carter's Liver Pills, and at the end of a few hours he was again X-rayed to see what effect, if any, the pills had had. Afterwards a fat meal was given the subject, and later a third picture taken to see what effect the fat had had on the biliary system. In summarizing the results of the experiments, the witness was questioned on direct and testified as follows:

> "Q. Well, based on any of the experiments, Doctor, what is your conclusion as to the results of Carter's Little Liver Pills, first, on the formation of bile by the liver? A. They have no effect on the formation of bile by the liver.
>
> Q. On the emptying of the gall bladder or causing the gall bladder to throw out bile?" A. It has no effect.
>
> Q. And, third, upon the flow of bile? A. It has no effect.
>
> Q. Doctor, when I was talking about the 'flow of bile' I mean the flow of bile through the duct and through the sphincter of Oddi into the intestine. You understood that? A. That is the only way it can flow. It can't flow any other way."

On cross, petitioner's counsel sought to inquire of the witness concerning the operation of the liver, gall bladder, and the ducts of the biliary system. Counsel for the Commission objected to the line of questioning as not being proper cross-examination. Petitioner's counsel remarked to the examiner that the questions were "right in line with the long discussion we had last night at the end of which you ruled I might explore into these things as a part of the biliary part of the functioning of the liver and gall bladder."

The examiner sustained the Commission's objection saying: "Since my ruling of last night, I have taken occasion to read over Dr. Case's examination in chief in great detail, and I must frankly admit that because of his testimony as to his qualifications, I was misled into thinking that he had been introduced as a gastroenterologist, instead of which a very careful reading of his testimony, from the beginning to the end, discloses that practically every question that was put to him on direct examination was based upon these pictures which he took as a Roentgenologist."

The examiner at this juncture turned to the witness and propounded a series of highly suggestive questions with the aim, so to speak, of cutting him down to size. At the conclusion he announced that he was going to change his ruling and limit cross-examination of the witness to the X-ray exhibits, "and anything that may properly be asked of him as to his qualifications in radiology, his interpretive readings of the various exhibits, and anything else that may appertain to the exhibits themselves."

Thereupon counsel for petitioner, after stating reasons thought to justify his attempted cross-examination, said:

> "Now if your Honor wants to rule that this man is qualified only to describe what appears in those pictures, I am satisfied with that ruling.
>
> Trial Examiner Purcell: Very well, sir.
>
> Mr. Hanaway: And I will move to strike out everything else that he said today.
>
> Trial Examiner Purcell: You mean on cross examination?
>
> Mr. Hanaway: On direct.
>
> Trial Examiner Purcell: On direct!
>
> Mr. Hanaway: Because he went way beyond that.
>
> Trial Examiner Purcell: Your motion to strike will be denied, and the ruling of the Examiner will stand. Confine your future examination to the pictures."

Now clearly it is not permissible for the Commission to qualify and use a witness for its own purposes as one having attainments in the field of gastroenterology, and then reduce him for purposes of cross-examination to the stature of a mere taker and explainer of X-ray pictures. We think that is what was done in this instance. As appears from the record excerpts quoted above, crucial questions put to Dr. Case were not confined to the X-ray exhibits but related generally to the *experiments* the witness had conducted. We agree with petitioner that more was involved in these experiments than a mere series of X-rays. The experiments were of the witness' own devising and were necessarily based on his familiarity with the physiology of the biliary system and the internal organs and on the vast number of cases he had previously examined. They dealt generally with the functioning of the gall bladder and bile and specifically with their functioning in respect of certain foods. In formulating the experiments as well as in interpreting them the witness was obviously required to draw extensively upon his knowledge of physiology and gastroenterology.[3]

It is argued that there was ample evidence from other quarters to sustain the findings and order of the Commission, hence the rulings, even if wrong, were not prejudicial. We are of opinion, however, that the cumulative effect of these unjustifiable restrictions on the cross-examination of key witnesses for the Commission was to deprive petitioner of a fair hearing. Such being the case the court is not disposed to speculate as to what would have been the outcome had a fair and impartial hearing been accorded. Inland Steel Co. *v.* NLRB, 7th Cir., 109 F. 2d 9; Empire Oil & Gas

[3] At a later stage of the proceedings petitioner subpenaed Dr. Case and offered to prove by him that he was president of the Battle Creek Food Company, producer and dispenser of a proprietary laxative in competition with petitioner, hence was an interested witness. The examiner rejected the offer on the ground that it came "too late," notwithstanding the case was still open for the taking of evidence.

Corp. *v.* United States, 9th Cir., 136 F. 2d 868, 871; Willapoint Oysters *v.* Ewing, 9th Cir., 174 F. 2d 676, cert. den. 338 U. S. 860. Cf. Reilly *v.* Pinkus, 338 U. S. 269.

The order of the Commission is set aside.

(Endorsed:) Opinion filed Jan. 19, 1953. PAUL P. O'BRIEN, Clerk.

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(4)

Opinion of Supreme Court On Prior Application By The Commission For Certiorari, Filed October 12, 1953. Reported In 346 U. S. 327.

FEDERAL TRADE COMMISSION *v.* CARTER PRODUCTS, INC.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

No. 114. Decided October 12, 1953

PER CURIAM.

Certiorari is granted and the judgment of the Court of Appeals is vacated. The cause is remanded to the Court of Appeals with directions to reinstate its prior judgment and order after amending it so that it specifically authorizes the Federal Trade Commission to open this proceeding for further evidence and a new order consistent with the Court of Appeals opinion herein. Cf. *Reilly* v. *Pinkus*, 338 U. S. 269, 277; *Labor Board* v. *Donnelly Garment Co.*, 330 U. S. 219, 224-228.

Mr. Justice Douglas dissents.

The Chief Justice took no part in the consideration or decision of this case.

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In the Supreme Court of the United States

OCTOBER TERM, 1959

No. 366

CARTER PRODUCTS, INC., PETITIONER

v.

FEDERAL TRADE COMMISSION

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE FEDERAL TRADE COMMISSION IN OPPOSITION

OPINIONS BELOW

The opinion of the Court of Appeals (Pet. App. 1–65) has been reported at 268 F. 2d 461. The opinion of the Federal Trade Commission (Pet. App. 66–75), has not yet been reported.

JURISDICTION

The judgment of the Court of Appeals was entered on July 28, 1959 (Pet. 1a–3a). The petition for a writ of certiorari was filed on August 31, 1959. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

The Federal Trade Commission found that petitioner had engaged in unfair and deceptive acts and practices by misrepresenting the therapeutic qualities

of its product, "Carter's Little Liver Pills." Among the misrepresentations were that petitioner's pills would stimulate the flow of bile by the liver. The Commission ordered petitioner to refrain from so stating, or from stating that its preparation had a beneficial effect upon the liver or had therapeutic properties other than laxative, and directed it to cease using the word "liver" in the trade name of its product. The questions presented are:

1. Whether the Commission's findings that petitioner had misrepresented the therapeutic properties of its product, found to be supported by the greater weight of the expert medical testimony, were invalid because the Commission did not further find that such medical testimony represented a concensus of informed medical opinion.

2. Whether the Commission exceeded the limits of its discretion to prescribe an appropriate remedy when, upon finding that petitioner's product had no effect upon the functioning or diseases of the liver, it required excision of the word "liver" from the trade name of the product.

3. Whether the court below applied the proper standard of judicial review.

STATEMENT

Petitioner manufactures and sells Carter's Little Liver Pills, a laxative product composed of two cathartics. In 1943 the Federal Trade Commission filed a complaint charging petitioner with unfair or deceptive acts or practices in violation of Section 5 of the Federal Trade Commission Act, primarily by

making a large number of misrepresentations in its advertising concerning the nature, operation and therapeutic effect of its preparation. After extended proceedings, the Commission in March 1951 found that petitioner had made a number of misrepresentations, and entered a cease-and-desist order. 42 F.T.C. 1137. The order was set aside by the Court of Appeals for the Ninth Circuit on the ground that the scope of cross-examination of three of the Commission's expert medical witnesses had been improperly restricted. 201 F. 2d 446. This Court, however, summarily vacated the judgment of the Court of Appeals, and remanded the case with directions to that court to authorize the Commission to reopen the proceedings for further evidence and a further order consistent with the Court of Appeals' opinion. *Federal Trade Commission* v. *Carter Products, Inc.*, 346 U.S. 327.

The Commission reopened the proceedings and allowed petitioner wide latitude in its extended cross-examination of the Commission's experts.[1] On the basis of the amended record the examiner issued a new recommended decision, again finding that petitioner had made a large number of misrepresentations in its advertising. After consideration of extensive exceptions, briefs and oral argument, the Commission (Commissioner Mason not participating) affirmed and entered a new cease-and-desist order. It issued a lengthy "Decision" incorporating entirely new findings of fact based on the amended

[1] One of the three doctors whose cross-examination had been held to have been unduly restricted by the examiner had since died. His entire testimony and the evidence introduced through him were stricken from the record (Pet. App. 2).

record, and an "Opinion" (Pet. App. 66–73) discussing some of the contested issues in the proceeding. The Court of Appeals unanimously affirmed (Pet. App. 1–65).

The Commission found (see Pet. App. 29–37), *inter alia*, that, contrary to the claims of petitioner, its pills did not "represent a fundamental principle of nature in self-treatment" for constipation; did contain strong medicine; was not "unqualifiedly safe"; would not have any therapeutic action, effect or influence on the liver; would not provide "two-way" relief; and would not have any value, except that provided by any effective laxative, in the treatment of headache, ugly complexion, bad breath, indigestion or a long list of terms used in the Carter advertising to describe general mental depression or physical debility. With respect to the only substantive issue here raised (Pet. 2)—whether petitioner misrepresented the effect of its product upon the flow of bile—the Commission found that the pills will not make bile flow freely or increase or beneficially influence the formation, secretion or flow of bile.

Most of the evidence was directed to the question of bile flow. The Commission's decision (R. Case No. 15373, Vol. 1, pp. 264–314[2]) contains a lengthy analysis of the extensive testimony and experimental evidence introduced both in support of and opposition to this claim (*id.* at 277–303). It concludes, for the

[2] The decision is not reported and, unlike the shorter explanatory "Opinion," is not reprinted in the Appendix to the petition. It is, however, part of the printed record in the Court of Appeals, which has been filed in this Court pursuant to Rule 21(3) and (4).

reasons discussed therein, that "the greater weight of the testimony and other evidence introduced into the record supports informed determinations that the preparation Carter's Little Liver Pills will not stimulate the formation of bile by the liver or increase the secretion of bile by the liver * * * [or] increase the flow of bile or any constituents thereof into the duodenum" (*id.* at 303–304; Pet. App. 36–37).

The Court of Appeals in its lengthy opinion of affirmance (Pet. App. 1–65) elaborately discussed and rejected petitioner's various contentions. It found substantial evidence in the record, viewed in its entirety, to support the Commission's finding that petitioner had misrepresented the effect of its pills upon the flow of bile (Pet. App. 61); and it determined, on its own "assessment of the evidence and testimony," that the Commission's evaluations of the weight and probative force to be given to the conflicting expert testimony on this matter "was not clearly wrong nor was it arbitrary" (Pet. App. 60). It also concluded that the Commission was acting "well within the orbit of its authority" in ordering the excision of the word "liver" from the trade name of petitioner's product (Pet. App. 62).

ARGUMENT

1. Petitioner's principal contention involves basically only an attack on the sufficiency of the evidence to support the findings—a contention which was rejected by the Court of Appeals after a careful study of the lengthy record. It contends (Pet. 20; see Pet. 18) that where there is a conflict of expert medical opinion with respect to the truth or falsity of the

therapeutic properties of a drug product, the Commission cannot accept the medical testimony that the claims are misleading unless it further finds that such testimony is in accord with "general medical agreement" or the "consensus of qualified medical opinion." We submit that there is no such limitation upon the Commission's right to evaluate the evidence and to make its findings thereon. The governing statute provides that "The findings of the Commission as to the facts, if supported by evidence, shall be conclusive" (15 U.S.C. 45(c)). The courts have repeatedly sustained orders of the Commission, directed against misrepresentations of the therapeutic value of medicinal preparations, as supported by substantial evidence, where the finding of misrepresentation was based upon the Commission's evaluation of conflicting testimony of medical experts.[1] They have done so without imposing any requirement of a further finding that the medical testimony credited by the Commission represents the consensus of informed medical opinion.

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[1] See *Alberty* v. *Federal Trade Commission*, 118 F. 2d 669, 670 (C.A. 9), certiorari denied, 314 U.S. 630; *J. E. Todd, Inc.* v. *Federal Trade Commission*, 145 F. 2d 858 (C.A.D.C.); *Irwin* v. *Federal Trade Commission*, 143 F. 2d 316, 323 (C.A. 8); *John J. Fulton Co.* v. *Federal Trade Commission*, 130 F. 2d 85, 86 (C.A. 9), certiorari denied, 317 U.S. 679; *Aronberg* v. *Federal Trade Commission*, 132 F. 2d 165, 170 (C.A. 7); *D.D.D. Corporation* v. *Federal Trade Commission*, 125 F. 2d 679, 680-6 (C.A. 7); *Dr. W. B. Caldwell, Inc.* v. *Federal Trade Commission*, 111 F. 2d 889, 891 (C.A. 7); *Neff* v. *Federal Trade Commission*, 117 F. 2d 495, 497 (C.A. 4); *Justin Haynes & Co.* v. *Federal Trade Commission*, 105 F. 2d 988, 989 (C.A. 2), certiorari denied, 308 U.S. 616. See also *Federal Trade Commission* v. *Raladam Company*, 283 U.S. 643, 646, in which as appears from the decision below (*Raladam Company* v. *Fed-*

Petitioner's reliance upon certain statements in the House Committee report on the 1938 Wheeler-Lea amendments to the Federal Trade Commission Act (Pet. 12–13, 15–16) is misplaced. These quotations related to a proposed amendment to the definition of "false advertisement" in 15 U.S.C. 55, which would have provided that an advertisement should not be considered false if it were supported by substantial minority opinion *and* if the advertisement "states clearly and prominently the fact of such difference of opinion". See H. Rep. No. 1613, 75th Cong., 1st Sess., p. 7.

The amendment, however, was not adopted. Furthermore, it did not relate to the Commission's authority, under Section 5 of the Federal Trade Commission Act, to issue cease and desist orders against false representations amounting to "unfair or deceptive acts or practices." It was, instead, proposed as a limitation on (1) criminal proceedings against certain types of false advertising and (2) the new authority conferred on the Commission to apply to a court for a restraining order or temporary injunction against disseminating such advertising pending completion of administrative Section 5 proceedings. Section 4 of the Act of March 21, 1938, amending the Federal Trade Commission Act, 52 Stat. 111, 114 (Wheeler-Lea Act, 15 U.S.C. 52–55). The definition of false advertising is expressly

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eral Trade Commission, 42 F. 2d 430, 433–435 (C.A. 6)) there was substantial conflict in the evidence of medical experts. This was also true in *Federal Trade Commission* v. *Raladam Company*, 316 U.S. 149. See 24 F.T.C. 475, 496.

applicable only to these new provisions for interim injunctive relief (15 U.S.C. 55; Pet. 9a). The limitations on "false advertising" embodied in the Wheeler-Lea Act do not restrict the authority of the Commission to issue cease-and-desist orders under Section 5. See *Justin Haynes Co.* v. *Federal Trade Commission*, 105 F. 2d 988 (C.A. 2), certiorari denied, 308 U.S. 616; *Fresh Grown Preserve Corp.* v. *Federal Trade Commission*, 125 F. 2d 917, 919 (C.A. 2); *Houbigant, Inc.* v. *Federal Trade Commission*, 139 F. 2d 1019 (C.A. 2), certiorari denied, 323 U.S. 763.

The cases cited by petitioner to support its argument are equally inapposite. Those arising under the 1906 Food and Drugs Act (*Seven Cases* v. *United States*, 239 U.S. 510; *United States* v. *Johnson*, 221 U.S. 488; *McLean Medicine Co.* v. *United States*, 253 Fed. 694 (C.A. 8)), or the postal fraud statute (*American School of Magnetic Healing* v. *McAnnulty*, 187 U.S. 94; *Reilly* v. *Pinkus*, 338 U.S. 269), involve imposition of criminal or other drastic sanctions because of past activities. Different considerations obviously apply where the proceeding involves a cease-and-desist order directed against future conduct. See *Reilly* v. *Pinkus*, *supra*, p. 277. *Belmont Laboratories* v. *Federal Trade Commission*, 103 F. 2d 538 (C.A. 3), alleged to be "in conflict" with the decision below (Pet. 40), clearly is not. There, in upholding a Commission order enjoining false claims about a skin disease remedy, the court merely referred to a treatise on "The Proposed Food and Drugs Act," which stated that under that Act the "test of truth" was the "gen-

eral agreement of medical opinion" (*supra*, at p. 543).[4]

2. There is no substance to petitioner's contention (Pet. 15; see 18–19) that, even if the Commission's findings are sustained, the Commission had no power to order the excision of the word "Liver" from its product's trade name; and that "the utmost extent of

[4] The two early Federal Trade Commission cases cited by petitioner (*L. B. Silver Co.* v. *Federal Trade Commission*, 289 Fed. 985 (C.A. 6), and *Raladam Co.* v. *Federal Trade Commission*, 42 F. 2d 430 (C.A. 6), affirmed on other grounds, 283 U.S. 643, are likewise unpersuasive. In *Silver* the court expressly stated that the finding of the Commission that there was only one brand of hogs rather than the two claimed by the company, was as "conclusive as other findings of fact made by that commission." It held, however, that in view of the conflict of opinion upon the subject, honest assertions of the two-breed viewpoint would not necessarily constitute "unfair methods of competition" (the only standard under Section 5 of the Trade Commission Act prior to the 1938 Wheeler-Lea amendments) "where the facts upon which such opinion is based are generally known to that part of the public [the purchasers of hogs] concerned in the controversy" (289 Fed. at 990). And in *Raladam* the court, after expressly distinguishing the *American School of Magnetic Healing* v. *McAnnulty* line of cases as involving a necessary showing of fraud, stated that "If, in the present case, the petitioner had claimed that Marmola [the product involved] would tend to reduce fat, and this claim had been proved untrue—even though the proof were only from a fair concensus of expert opinion—it would not be important, for some purposes, that the petitioner believed the claim to be true" (42 F. 2d at 435). It was, however, admitted there that Marmola was an effective treatment for obesity, and in such circumstances the court refused to sustain an order requiring a statement that Marmola was unsafe unless taken with medical supervision, in the absence of some more adequate showing that "competition" with some *bona fide* remedy was injured by the lack of such a statement.

the Commission's jurisdiction is to require a statement of the difference of [medical] opinion to be made in the advertising". "Congress ha[s] placed the primary responsibility for fashioning orders upon the Commission" (*Federal Trade Commission* v. *National Lead Co.*, 352 U.S. 419, 429), and the Commission necessarily has "wide discretion" in determining the remedy "'deemed adequate to cope with the unlawful practices' disclosed by the record" (*Federal Trade Commission* v. *Mandel Bros., Inc.*, 359 U.S. 385, 392). This discretion has been held to extend to the deletion of misleading words in brand names. *Jacob Siegel Co.* v. *Federal Trade Commission*, 327 U.S. 608; *Federal Trade Commission* v. *Algoma Lumber Co.*, 291 U.S. 67. Since the Commission found that petitioner's pills have no effect upon the functioning or diseases of the liver, it did not abuse its "wide discretion" in concluding that, in order to cure the misrepresentations, petitioner should stop describing its product as a "liver" pill.

3. There is no merit to petitioner's claim (Pet. 36–39) that the court below did not properly perform its function as a reviewing court. This argument appears to stem from the relatively brief discussion in the court's opinion of petitioner's principal contention here (which was only a minor point below), that the Commission was precluded from finding the bile flow representations to be false in view of certain medical testimony to the contrary. The court fully considered and rejected petitioner's arguments as to

the proper standard of proof in Commission proceedings (Pet. App. 51–53, 58–60).

Petitioner also apparently contends that the court was arbitrary in accepting certain experimental data introduced by Commission witnesses, while rejecting or discounting the experimental data adduced by petitioner's experts. This is but another challenge to the sufficiency of the evidence. The court properly refrained from substituting its own evaluation of the technical testimony for that of the Commission (see *Federal Trade Commission* v. *Algoma Lumber Co.*, 291 U.S. 67; *Corn Products Refining Co.* v. *Federal Trade Commission*, 324 U.S. 726, 739). However, it carefully considered petitioner's arguments on this point, as well as the contention that the Commission was biased or unfair or had "abdicated" its "duty to weigh or consider the evidence" (Pet. App. 60–61). It made a careful "scrutiny of the entire record", including a "fair estimate of the worth of the medical testimony of the expert witnesses" (*id.* at 58), and discussed the experimental evidence in some detail (*id.* at 6, fn. 4; 48–50). It concluded that the Commission's findings and conclusions were based on substantial evidence in the record as a whole (*id.* at 61), that the evaluation of the expert testimony was "not clearly wrong nor * * * arbitrary" (*id.* at 60), and that petitioner's objections to the fairness of the Commission's proceedings were "without real substance or merit" (*id.* at 61). Such a thorough examination of the order fully meets the standards for judicial review of agency action.

CONCLUSION

The decision below is clearly correct and this case presents no substantial question warranting review by this Court. The petition for a writ of certiorari should be denied.

Respectfully submitted.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1959

No. 366.

CARTER PRODUCTS, INC.,

Petitioner,

v.

FEDERAL TRADE COMMISSION,

Respondent.

PETITIONER'S REPLY BRIEF.

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POINT II.—The lower Court's erroneous deference to the Commission's supposed "special competence" in controversial medical matters stultified all adequate judicial review on its part of the issues in this case. Its effect was to constitute judicial abdication and to make the Commission the final arbiter of scientific truth.

The Court's declaration of its total inability to deal with medical issues nullifies the Court's finding that the Commission's decision was supported by substantial evidence and demonstrates that no proper judicial review has been had.

The General important public consequences of this error in imputing to the Commission special competence and sovereign decisional power in controversial scientific matters constitute further grounds for the granting of a writ of certiorari in this case and present questions involving the interpretation of a Federal Statute which have not been, but should be, settled by this Court 6

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No. 366

CARTER PRODUCTS, INC.,

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v.

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Respondent.

PETITIONER'S REPLY BRIEF.

POINT I.

THE LEGISLATIVE HISTORY AND COGENT REASONS OF POLICY NEGATIVE CONGRESSIONAL INTENT TO CONFINE THE APPLICATION OF THE STATUTORY STANDARD OF PROOF OF FALSITY OF THERAPEUTIC CLAIMS TO CRIMINAL PROCEEDINGS.

IRRESPECTIVE OF CONGRESSIONAL INTENT, THE DUE PROCESS CLAUSE'S REQUIREMENTS OF CERTAINTY AND DEFINITENESS OF STATUTORY STANDARDS APPLY TO CIVIL STATUTES AND PROCEEDINGS UNDER THEM AS WELL AS TO CRIMINAL STATUTES, AND, INDEPENDENTLY OF STATUTORY CONSTRUCTION, IMPEL THE APPLICATION IN THIS CASE OF TH. DEFINITE STANDARD OF PROOF OF FALSITY BY GENERAL INFORMED MEDICAL AGREEMENT.

(1) The language of the Committee Reports contains no suggestion that the constitutional problem posed by the suppression of therapeutic claims, where medical opinion

is in substantial disagreement, is limited to situations involving the imposition of criminal sanctions. The legal authorities cited by the Committees as raising constitutional issues did not concern exclusively penal statutes. The legislative statements contain no reference to fraudulent intent which renders an advertisement subject to criminal sanctions under the provisions of the Federal Trade Commission Act contained in Section 54, Title 15 U. S. C. (Petition, App. B p. 8a).

The same constitutional considerations apply, in any event, because to render acts *unlawful*, and to subject them to *all-time proscription* by permanent injunction, is most certainly a drastic penalty equally as disastrous to a company or individual engaged in the sale of drugs as a fine or other criminal sanctions. To permanently prohibit a statement of the therapeutic effect of a drug is under normal marketing conditions to prohibit altogether its effective sale.

Quite apart from statute, "The principle of due process of law requiring reasonable certainty of description in fixing a standard for exacting obedience from a person in advance has application *as well in civil* as in criminal legislation * * *." *Cline* v. *Frink Dairy Co.*, 274 U. S. 445, 463; and more particularly here, where the statute confers the extraordinary remedy of injunctive process where the necessity of the clearest sort of proof for the granting of such drastic relief is axiomatic independently of constitutional considerations.

(2) To apply the questionable holding of the Court in *Fresh Grown Preserve Corp.* v. *Federal Trade Commission*, 125 F. 2d 917 (2d Cir.) (Commission's Brief, pp. 7-8) that the definition of false advertising is only relevant in a criminal proceeding or in a temporary injunction proceed-

ing under Section 53, Title 15 U. S. C. to therapeutic claims has no bearing on this case in any event and would not only be to ignore the entire legislative history of the 1938 amendments but to create without reason different standards for a permanent Cease and Desist Order and for a preliminary injunction or criminal proceeding. Why should the determination of the question of falsity of therapeutic claims and *consensus of medical opinion as an objective test of falsity* be any different in a proceeding for a temporary and a permanent injunction or in a proceeding involving criminal sanctions? Why should a permanent injunction issue on less or different proof than a merely temporary one so far as therapeutic claims are involved?

In the *Fresh Grown Preserve* case what the Court said was in answer to a claim that there had been in fact no advertising and that labelling was excluded from the jurisdiction of the Federal Trade Commission by the express terms of Section 55(a), Title 15 U. S. C. The case was further based on unfair competition. In any event the later cases are in direct conflict with this case and have construed the Wheeler-Lea amendments as applying also to Cease and Desist Orders under Section 45, Title 15 U. S. C.; *Irwin* v. *Federal Trade Commission*, 143 F. 2d 316 (8th Cir.) footnotes p. 319; *Alberty* v. *Federal Trade Commission*, 182 F. 2d 36 (U. S. C. A. Dist. of Col.), footnotes pp. 37, 38, cert. den. 340 U. S. 818; *Consolidated Royal Chemical Corp.* v. *F. T. C.* (7th Cir.) 191 F. 2d 896, pp. 898, 899; *Koch* v. *Federal Trade Commission* (6th Cir.) 206 F. 2d 311, p. 315; *Rhodes Pharmacal Co.* v. *F. T. C.* (7th Cir.) 208 F. 2d 382, p. 387.

Apart from Legislative history or statutory construction the same basic constitutional need for a fair and objective standard of truth in the case of therapeutic claims exists whether they are treated as falling under

Sections 45 or 52 and 55, of Title 15 U. S. C. and whether they involve criminal sanctions or the equally drastic civil sanctions imposed by the Act. The fact that false advertising may also have criminal consequences under Section 54, Title 15 U. S. C., only supplies a greater constitutional necessity for such a standard.

(3) The legislative histories of the Food and Drug Act and of its companion legislation, the Wheeler-Lea Amendments of 1938, are both relevant because the two Acts are in *pari materia*. *U. S. v. C. I. O.*, 335 U. S. 106. Contemporary commentary on the legislative history of both Acts and on similar legislative proposals support the Petitioner's interpretation of the Wheeler-Lea Amendments.

The comments of Professor Handler on False Advertising Under the Wheeler Lea Act, Vol. VI, Law and Contemporary Problems, made at the time of the enactment of the Wheeler-Lea Amendments are to the effect (footnote 24, p. 94) that proof of falsity by "general consensus of informed opinion" removes the constitutional objection. "It is not impossible to show that a therapeutic claim is at variance with the general consensus of informed and scientific opinion" (100).

S. 1944, 73rd Congress, 1st Sess. (1933), the Tugwell Bill, a proposed amendment to the 1906 Drug Act, forbade in Section 9(b)(2), "any representation, directly or by ambiguity or inference, concerning the effect of such drug which is contrary to the general agreement of medical opinion". Commenting on this proposal Professor David F. Cavers of Duke University Law School, editor of Law and Contemporary Problems, said (Vol. VI, Law and Contemporary Problems, 1939, p. 34), "* * * since the truth or falsity of therapeutic claims must often rest on opinion evidence and since expert opinion may differ, it was felt

essential to provide a criterion of opinion evidence sufficiently definite to avoid the risk that the provision would be held unconstitutional for want of certainty."

Commenting on the proposed Food and Drug Act—Fisher, "The Proposed Food and Drugs Act", Vol. I, Law and Contemporary Problems, p. 95, says, "Making, the state of opinion in the medical world determinative of falsity as to statements concerning the effects of drugs seems radical; actually, the present Act has ventured that far. For under judicial decision, the therapeutic vatication scored by the present Act is not 'false' if there exist a real difference of opinion between rival schools of medical practitioners; aliter, if the concensus of the medical world denies its truth. The contribution of the bill in this regard is that a statutory definition of falsity is provided, which, capable of explanation by regulation, should result in greater uniformity and success of administration." "* * * the bill makes general medical opinion the test of falsity * * *." (footnote, pp. 96-97)

It is clear that the constitutional requisite of certainty is the same for both Acts and it is also clear, as this Court in *Seven Cases* v. *U. S.*, 239 U. S. 510 (517), said of the 1912 amendments to the Food and Drug Act, that the legislative history of the Wheeler-Lea Amendments to the Federal Trade Commission Act show that "Congress deliberately excluded the field where there are honest differences of opinion between schools and practitioners."

(4) The Commission has failed to meet the destructive effect on its contentions of the decision in *Alberty* v. *Federal Trade Commission*, 182 F. 2d 36, cert. den. 340 U. S. 818 (Petition pp. 16-17) and has failed to deny, because it cannot deny, that the lower Court found the existence hereof a substantial conflict in the status of medical opinion on the basic issue involved a finding which is amply

supported by the record (Petition pp. 19-34). There is thus no necessity of remand, and this Court is requested to grant the primary relief requested in the Petition, paragraph (a) page 42.

POINT II.

THE LOWER COURT'S ERRONEOUS DEFERENCE TO THE COMMISSION'S SUPPOSED "SPECIAL COMPETENCE" IN CONTROVERSIAL MEDICAL MATTERS STULTIFIED ALL ADEQUATE JUDICIAL REVIEW ON ITS PART OF THE ISSUES IN THIS CASE. ITS EFFECT WAS TO CONSTITUTE JUDICIAL ABDICATION AND TO MAKE THE COMMISSION THE FINAL ARBITER OF SCIENTIFIC TRUTH.

THE COURT'S DECLARATION OF ITS TOTAL INABILITY TO DEAL WITH MEDICAL ISSUES NULLIFIES THE COURT'S FINDING THAT THE COMMISSION'S DECISION WAS SUPPORTED BY SUBSTANTIAL EVIDENCE AND DEMONSTRATES THAT NO PROPER JUDICIAL REVIEW HAS BEEN HAD.

THE GENERAL IMPORTANT PUBLIC CONSEQUENCES OF THIS ERROR IN IMPUTING TO THE COMMISSION SPECIAL COMPETENCE AND SOVEREIGN DECISIONAL POWER IN CONTROVERSIAL SCIENTIFIC MATTERS CONSTITUTE FURTHER GROUNDS FOR THE GRANTING OF A WRIT OF CERTIORARI IN THIS CASE AND PRESENT QUESTIONS INVOLVING THE INTERPRETATION OF A FEDERAL STATUTE WHICH HAVE NOT BEEN, BUT SHOULD BE, SETTLED BY THIS COURT.

Introduction of this issue is rendered necessary by the Commission's contention (its Brief, p. 11) that the lower "Court properly refrained from substituting its own evaluation of the technical testimony for that of the Commission"; and is further an inseparable incident of the determination of the questions presented in the Petition.

A.

The Nature and Important Public Consequences of the Error.

The extreme to which the lower Court has pushed the doctrine of deference to the expert judgment of an administrative agency constitutes judicial abdication. It has three effects—first, it makes the Commission the final arbiter of the truth of scientific matters; second, it strips the Petitioner of its statutory right of judicial review, and third, it insures against all effective judicial scrutiny of such issues.

Said the lower Court, "The judges of this Court are not equipped by education, training or experience to resolve a factual question of this character which obviously concerns the accuracy of the respective views of men practising the art of medicine" (Opinion, App. 52). "* * * the evaluation of the Commission as to the weight to be given such testimony *concerning medical truths was a matter committed for decision to the informed judgment of the Commission* * * *." So far as concerns any conflicts in such testimony, we are also of the view that all such conflicts presented questions of fact *for resolution by the Commission and not for resolution by this Court.*" (Opinion Appendix, 58). "* * * *our views would have to yield to the specialized experience and knowledge of the Commission*" (Opinion App. 52).

The lower Court's avowal of its lack of training and equipment to pass on scientific matters is a strange confession of judicial impotence in the light of the myriad of intricate scientific problems with which federal courts wrestle daily in the fields of physics, chemistry and medicine both in patent, personal injury, food poisoning cases and in cases arising under the Federal Food, Drugs and Cosmetics Act.

Previous decisions of the Courts of Appeals—including those cited by the lower Court in its Opinion (App. 53, and footnote, p. 58) and by the Commission in its Brief (pp. 6-7)—have merely treated medical issues as any other issues of fact would be treated and have not placed their resolution on the ground that the Commission possessed special competence in scientific matters. The present decision, by creating an immense special province in which the Commission is impregnable to effective judicial review, has introduced a dangerous innovation and a hitherto unknown restriction on the jurisdiction of courts which review the Commission's determinations in the field of medical and scientific matters. Mr. Justice Jackson, with whom Mr. Justice Frankfurter concurred, in his dissenting opinion in *Securities Commission* v. *Chenery Corp.*, 332 U. S. 194, 209-218, sounded a warning against such undue judicial deference to administrative experience. "His warning", says Professor Jaffe* "against the loose application of the concept of expertness was warranted and timely." That warning finds its clearest application here.

B.

The Inherent Impossibility of Congressional Intent to Vest This Lay Commission With Special Expert Judgment in Controversial Scientific Matters.

Of inherent necessity administrative determinations of fact in the realm of one of the world's four great principal sciences can "not embody the results of any specialized departmental knowledge or experience." *Haggar Co.* v. *Helvering*, 308 U. S. 389, 398. As Professor Jaffe says,

* "Judicial Review: Question of Law", 69 Harvard Law Review 239, 271.

loc. cit., "* * * the assumption that expertness is relevant can, if mechanically invoked, become ludicrous." Medical science is divided into hundreds of specialized classifications. Even the general practitioner has no special competence in any one of these separate specialized fields. The science of therapeutics itself ranges over hundreds of human diseases and disorders, functional or organic; it involves an intimate knowledge of physiology, anatomy and pathology whose literature fills the libraries of the world. To say that the legislature committed to the expert judgment of this lay Commission the final resolution of scientific controversies in one of the most controversial subjects in all of medical science—the physiology of the human liver—carries with it its own refutation. But the fallacy of the lower Court's holding does not end here. The Commission's jurisdiction extends to the false advertising of all types and kinds of products including those involving the use of the principles of the sciences of physics, mechanics, chemistry, biology and electronics. The reasoning of the Court would necessarily impute to this lay Commission the possession of expert judgment *in the whole realm of applied science.*

C.

The Legislative History and the Generalized Nature of the Commission's Activities and Jurisdiction Confirm the Impossibility of Such Congressional Intent.

The legislative history shows that there was no intention to repose special confidence in the Commission's expert judgment in medical or scientific matters. The following colloquy ensued between Representative O'Malley and Representative Lea, co-proponent of the Wheeler-Lea Amendments to the Federal Trade Commission Act (Con-

gressional Record—House, January 12, 1938, p. 421, Vol. 83, Part 1, 75th Congress, 3rd Session):

> "Mr. O'Malley: Does the gentleman feel that the Federal Trade Commission, composed of laymen, could decide what was responsible medical opinion?"
>
> "Mr. Lea: No."

The Minority Report ("Additional Views" appended to the House Report 1613 on the Wheeler Lea Amendments, p. 25) stresses the superior equipment of other agencies which have "a scientific personnel more competent to deal with the technical questions involved" and emphasizes, as an objection to the efficacy of the amendments, that, as regards the Commission's determination that "it has reason to believe that the advertisement is false or misleading" * * * "it only would be able to come to this conclusion after getting evidence and *expert advice* with regard to the matter from the technicians of the Food and Drugs Administration*, unless a *duplicate* technical staff is to be established."

Identical considerations were voiced by Senator Copeland (Congressional Record, March 14, 1938, p. 3288):

> "Complex scientific questions continually arise in the administration of laws dealing with the purity and wholesomeness of our food and drug supplies. To meet these questions the Food and Drug Administration has built up a competent scientific staff. No such staff exists in the Federal Trade Commission. It will not do to say that the staff of the Food and Drug Administration will serve the Federal Trade Commission in the administration of the false advertising law. No administrative officer can deal effectively with problems as they arise without having

* But Congress has refused to commit the determination of therapeutic issues to the special competence even of that agency and has required such determinations under the Food, Drug and Cosmetic Act to be made by courts and juries in libel proceedings.

immediately and continuously at his command the technical advice of experts in the field to which the questions relate."

An examination of the Commission's published official Annual Reports discloses that to date no such duplicate scientific staff has been built up. The cases involving therapeutic claims presented to the Commission range over the entire field of medicine. Each case, like the present case, presents a new medical problem never before determined by the Commission*. There is no pattern of recurring medical issues from which experience may produce expertness, such as occurs, for example, in the cases of occupational hazards or diseases handled by Workmen's Compensation Commissions. It is impossible that this lay body's determination of one of the most highly controversial subjects in the whole field of therapeutics should be the *product* of *administrative* experience. The activities of this lay Commission are further of the most diffuse and generalized character, ranging over the whole field of national trade practices. Aside from its functions concerning unfair and deceptive trade practices in general, the Commission is presently also an enforcement agency of the provisions of Sections 2, 7 and 8 of the Clayton Act, the Webb-Pomerene Export Trade Act of 1918, the Wool Products Labeling Act and Fur Products Labeling Act; the Flammable Fabrics Act, the Lanham Trade Mark Act and the textile fibre products and packing and stockyards acts P.L. 85-909, Sept. 2, 1958 and P.L. 85-897, September 2, 1958. Its Annual Report for 1958, p. 7, indicates that the Com-

* As Mr. Justice Frankfurter and Mr. Justice Jackson indicated in their dissenting Opinion in the *Cheney* case, (332 U. S. p. 213), it is a contradiction in terms to say that an administrative agency "must be sustained because of its accumulated experience in solving a problem with which it had never before been confronted".

mission is seeking still further legislative expansion of its jurisdiction. Even if it were otherwise possible for a lay body to acquire special competence in the art of medicine as a whole, the pressure of the performance of such generalized functions would preclude the specialization requisite to produce expertise in the intricate and difficult realm of medical science.

D.

The Lower Court's Application of the Doctrine of Administrative "Special Competence" is In Conflict With the Decisions of This Court.

Analysis of this Court's decisions establishes that the expert judgment of the Commission and like agencies extends to factors such as to the shaping of appropriate remedies, the appraisal of adverse effects on competition, questions of consumer confusion, the interpretation and meaning of advertisements and the effects of the use of advertising media and of other common trade practices where the agency's experience with recurrent special problems has necessarily developed special competence and knowledge from constant practice and experience. *Moog Industries, Inc.* v. *F. T. C.*, 355 U. S. 411, 413; *Security Administrator* v. *Quaker Oats Co.*, 318 U. S. 218. Further than that, the decisions of this Court have not gone.

So ardent a protagonist of the administrative process as Professor Kenneth Culp Davis states in his recent "Administrative Law Treatise" 1958, (Vol. 4, Section 30.09, p. 245, footnote 14), "a court of generalists performs a useful function when it provides a needed check on a tribunal of specialists even if the specialists are chemists". Here the Commission is not composed of specialists but of laymen.

After a comprehensive review of all of this Court's decisions on the doctrine of administrative expert judgment, Professor Davis extracts from those cases the conclusion (op. cit.; Vol. 4, Section 30.07, p. 232) that substitution of *judicial* for administrative judgment is indicated where, *as in the instant case*, the problems "transcend the single field of the particular agency" or "are affected substantially by constitutional considerations, whether or not a constitutional issue is directly presented" or "require analysis of legislative history * * *". All of these considerations opposed to judicial deference to administrative special competence are present in the case at bar.

E.

The Vitiating Effect of the Error on the Lower Court's Review of This Case.

If, as the lower Court protests, the Court was totally unable to cope with medical issues, the Court was also necessarily, by the same token, equally unable to decide whether the Commission's resolution of such issues was or was not supported by substantial evidence. In consequence there has not been afforded to this Petitioner the judicial review to which it is entitled as a matter of right by the Federal Trade Commission Act and the Federal Administrative Procedure Act. Only such counsels of despair on the lower Court's part can account for the fact that it made no attempt to pass specifically on the multitude of self-declared and self-evident defects in the tests and testimony of the Commission's expert witnesses to which the lower Court's attention was directed in the utmost detail by the Petitioner's Briefs. There can be no doubt in the nature of things that the Court of Appeals' confession of complete judicial incompetence in the face of medical issues was not

only bound to influence the character of its review but to reduce the Court to a mere rubber stamp for the Commission. The same self-declared incapacity which vitiated the Court's resolution of patent defects in the Commission's medical proof, rendered the Court powerless to apply—even if it had been willing—the special standard of certainty in the proof of the falsity of therapeutic claims imposed by the Wheeler-Lea Amendments to the Federal Trade Commission Act. Correction of this error is therefore necessary to a proper application of the standard of proof of falsity of therapeutic claims by general medical informed agreement imposed by the Act.

October 5, 1959

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FILE COPY

No. 366

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1959

CARTER PRODUCTS, INC.,

Petitioner,

against

FEDERAL TRADE COMMISSION,

Respondent.

PETITION FOR REHEARING OF ORDER DENYING PETITION FOR WRIT OF CERTIORARI.

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Here there is neither proof nor is there finding on the part of court or commission either of the existence of such a consensus of opinion or that disproof of Carter's claim was established thereby.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1959.

No.

CARTER PRODUCTS, INC.,

Petitioner,

against

FEDERAL TRADE COMMISSION,

Respondent.

PETITION FOR REHEARING OF ORDER DENYING PETITION FOR WRIT OF CERTIORARI.

Carter asks this Court to grant rehearing of its Order of November 9, 1959* denying Carter's Petition for a Writ of Certiorari, No. 366, filed September 1, 1959, because of substantial grounds available to Petitioner although not previously presented, within the purview of this Court's Rule 58.

Questions Presented.

The questions presented are:

(1) Does the Commission's Cease and Desist Order constitute an assumption of jurisdiction in a case not covered by the Federal Trade Commission Act because in the circumstances of this case the assertion of the therapeutic claim amounts to advocacy of a medical opinion which is not

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* The issuance of the Order has been stayed by Order of Mr. Justice Douglas dated November 10, 1959, pursuant to Rule 25, pending disposition of this Petition for Rehearing.

a representation of fact capable of disproof? (*infra*, pp. 12-14).

(2) Is the decision of the Court below in conflict with the chain of precedent of other Federal Circuit Courts of Appeals and with the principles of the decisions of this Court which establish that disproof by consensus of informed medical opinion is an indispensable prerequisite to the conversion of an assertion of a therapeutic claim or medical opinion into a representation capable of disproof as a fact? (*infra*, pp. 15-21), and

(3) Is the advocacy by this therapeutic claim of an honest, harmless medical opinion included "in the web of freedoms which make up free speech", *Speiser* v. *Randall*, 357 U. S. 513, 520, and protected against permanent suppression by the Commission's Order in this case under the guarantee of the First Amendment to the Federal Constitution? (*infra*, pp. 21-25).

For reasons hereafter set forth Carter submits in good faith that the questions presented are of prime, private and public importance, undetermined by this Court*, which neither the age of this litigation, the size of the record, the length of the lower Court's Opinion, nor the precise amount of damage to this Petitioner occasioned by the Commission's Order should deter this Court from reviewing.

As to the last, damage follows as matter of course for banishment of a manufacturer's claim of the therapeutic efficacy of a drug inevitably results under normal marketing conditions and will result here in diminution, if not prohibition, of effective sale. First Amendment guarantees are,

* "The extent to which such [false, commercial] advertising can be regulated consistently with the First Amendment has [not] never been authoritatively determined". *Commonwealth* v. *U. S.*, 358 U. S. 498, concurring Opinion of Mr. Justice Douglas, footnote p. 513.

at all events, however, based on transcendent considerations; their application is independent of any showing of monetary harm.

As to the factors of age of the litigation and size of the record, Carter is responsible for neither. Protraction of this litigation was occasioned predominantly by the Commission's original delay of some five years in its first decision of the case after the cause was originally submitted to that body (App. Opinion, pp. 21-22). Subsequent delay is due primarily to the tactics of the Commission which rendered its first decision abortive as a plain denial of due process. (See original decision of the Court below, 201 F. (2) 446, and of this Court 346 U. S. 327 App. pp. 76-91). Enlargement of the record is accounted for mainly by the Commission's indulgence of its prosecutor's cross-examination of Carter's expert witnesses for days on end,* by the interminable discourses of the Hearing Examiner and the endless interruptions and objections of counsel for the prosecution,** accounting for some two-thirds of the record.

The questions now and previously presented by Carter's Petition No. 366 raise issues of law only. This Court's task of review is rendered minimal by the lower Court's finding that the difference in the status of informed medical opinion on the basic medical issues involved was in fact so substantial that the Court declared its total inability to resolve that difference. (App. Opinion, p. 52).

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* Cross-examination of one of Carter's witnesses alone, Dr. Killian, consumed 33 days and 800 pages of the original stenographic record.

** The Commission's Hearing Examiner rebuked the prosecutor for such tactics (No. 15373, Vol. VIII, 3291, saying "I have had to fight that very thing at almost every step of it is proceeding since it has been reopened, because of your objections" * * *", and repeated that rebuke in his formal 'Supplementary Report' (No. 15373, Vol. I, 194).

That task is further reduced by the fact that the Commission, in its Brief in Opposition, both fails to deny Carter's assertions as to the state of the record in this regard and the effect of the Court's finding of wide divergence of medical opinion on the basic issues and takes the position that as matter of law the Commission alone is empowered to resolve finally all differences in the state of medical opinion and all medical controversies however pronounced they may be. The Commission flatly asserts that courts should not in such matters substitute their judicial judgment for that of the Commission (Commission's Brief In Opposition, pp. 6, 7, 11).

The Commission's decision contains no finding that the falsity of the claim has been established by consensus of informed medical opinion or by test methods approved by such consensus, and none can be implied. *U. S.* v. *Chicago M. St.-P. & P. R. Co.*, 294 U. S. 499, 504-5; *Atchison Ruy.* v. *U. S.*, 295 U. S. 193, 202; *Securities Commission* v. *Chenery Corp.*, 318 U. 80, 94; *Secretary of Agriculture* v. *U. S.*, 347 U. S. 645, 654.

The issues here are therefore issues of law which may be briefed, reviewed and disposed of by this Court on the basis of normal sized briefs well within the maximum compass prescribed by its Rules.

Finally, as to the length and semblance of meticulous care of the lower Court's Opinion: This 65 page Opinion consists literally almost entirely of recitals of the history of the litigation, *verbatim* recitations of the allegations of the complaint, of the answer, of the minute details of Carter's advertising, of the specific provisions of the Commission's Findings and Order, copious footnotes quoting among other matters, again *verbatim*, Carter's summary of its assignments of errors, and the rest of generalities of discussion and issues not involved here. Out of its 65 pages,

a single sentence (p. 51) deals parenthetically with Carter's major legal contention concerning the effect of the Wheeler-Lea Amendments to the Federal Trade Commission Act, approximately a page (pp. 51-52) with the basic issue of consensus of informed medical opinion and no single word of specific treatment or discussion is contained in the entire Opinion of the carefully record documented fatal defects in the Commission's proof and test methods (summarized here briefly in the Petition for Certiorari, pp. 21-39) to which 100 pages of Carter's Briefs below were directed.

Statement Of Case, Including Certain Circumstances Not Previously Drawn To This Court's Attention.

The Commission's Order, enforced by the Court of Appeals for the Ninth Circuit, permanently enjoins Carter from advertising that the drugs in its product are an effective aid to bile flow, and similarly forbids the use of the word "Liver" in its trade name. The drugs in question are aloes and podophyllin, vegetable drugs of the same plant kingdom as the wonder drug penicillin. Carter sought review by certiorari of these provisions of the Order as respects this basic truthful claim only. It asserts no right to make and asks no modification of the Order prohibiting extravagant claims.

The record discloses that the claim of effectiveness is an honest and harmless therapeutic claim supported by a formidable body of informed medical opinion. (Record references, Petition for Certiorari, pp. 21-38).

The universality of scientific recognition of the truth of Carter's claim, current prior to the commencement of these proceedings, may be seen at a glance by consulting any standard encyclopedia whose function it is to reflect

consensus of informed opinion.* The article on Diseases of the Liver, Vol. 14, p. 240, the New International Encyclopedia (Second Edition, Dodd, Mead & Company), for example, states "Drugs which have especial action on the liver (cholagogues) are given to promote the flow of bile and to overcome constipation. Among the more important of these are mercury in the form of blue mass and calomel, *podophyllin*, nitro muriatic acid, and the saline purgatives". The Encyclopedia Britannica (11th ed.), Vol. XXI "Podophyllin", states that "when taken internally it is both a secretory and an excretory cholagogue", i. e., an aid to bile flow.

Such scientific recognition of Carter's claim was established both by its own experimental proof and by a formidable body of testimony and of medical literature and authority created in part by the published writings of the Commission's own experts adduced in the record (Petition, pp. 29-31). The Court below declared the conflict in the status of informed medical opinion so great that it professed its inability to cope with it and described this issue as the vital area of controversy in this case (App. Op. 34), attesting to its formidable nature by referring to the "huge mass of medical testimony" which dealt with these issues. (App. Op. 52)

The Commission's determination of falsity is based on tests of the drugs performed on animals only. The Commission now, however, concedes in its official Annual Report for 1955, p. 28, that such tests are totally inadequate to assay the effectiveness of drugs because "It is not possible

* Use of such standard reference works by appellate courts is sanctioned by this Court's practice and decisions in *Jacobson* v. *Massachusetts*, 197 U. S. 11; *Brown* v. *Board of Education*, 347 U. S. 483; by *Belmont Laboratories* v. *Federal Trade Commission*, 103 F. (2) 538, 539; *Kelly* v. *Maryland Casualty Co.*, 45 F. (2) 782, 784-5 and a host of authority collated in *Wigmore On Evidence*, 3 ed. Vol. 6, Sect. 1700 p. 21.

to test the truth or falsity of the claims made for the new ingredients without having them subjected to *clinical and hospital tests*". The truth of this now official admission, destructive of the test methods used by the Commission in reaching its conclusions in this case condemning the claims of Carter's drugs, is confirmed by the uniform practice of the Commission's co-ordinate agency, the Federal Food and Drug Administration to demand that animal tests of drugs be supplemented by tests on humans (Petition, p. 32) and represents further a natural phenomenon of such universality that this Court may take judicial notice of it*.

Summary Of Grounds Originally Urged In Support Of The Petition And Added Factors Demonstrating The Error Of The Lower Court's Decision.

This summary is furnished here both because it is essential in order to place the questions now presented in their proper perspective and also because this Court's decision in *Flynn* v. *U. S.*, 348 U. S. 909, 99 L. ed. 1298, is assurance that denial of a petition for a writ of certiorari is neither an irrevocable nor definitive act of this Court beyond its reconsideration or recall, and that consideration of petitions for rehearings "is not to be deemed an empty formality as though such petitions will as a matter of course be denied" (99 L. ed. 1299).

The principal grounds urged in support of the Petition were:

(1) The legislative history of the Wheeler-Lea Amendments to the Federal Trade Commission Act (Petition,

* The Encyclopedia Britannica (11th ed.), Vol. XXI "Pharmacology", states "some species of animals are much more susceptible to the action of certain drugs than others, a condition which depends on obvious or unknown structural or metabolic differences."

pp. 10-18) and commentary on those Amendments at the time of their enactment (Petitioner's Reply Brief, pp. 4-5) demonstrate that:

Congress recognized that constitutional requisites of certainty in the Act imposed by the due process clause of the Fifth Amendment and important considerations of policy forbade it to place drug product therapeutic claims at the mercy of the *individual* opinions of any one group of experts where (a) the subject, as here, concerns an unsolved medical controversy* regarding which general informed medical opinion is itself in a state of wide disagreement, and where (b) the lower Court, as here, has found** both an entire absence of general informed medical agreement and a substantial difference in general informed medical opinion itself as to the truth or falsity of the particular therapeutic opinion and the test methods used by the Commission to determine its falsity.

In such a case the clearly demonstrated Congressional intent was to make general informed medical opinion or consensus of opinion the test of falsity of a claim of effectiveness of a drug in order to supply the necessary and otherwise missing objective and certain standard by which an administrative determination by a lay body of the falsity of the claim could in the first place be guided and in the second place reviewed by the courts. The Commission failed to apply this standard or to prove and find that the falsity of the claim had been established by that standard or by test methods thereby approved (Petition, pp. 20-21).

The Court below made no disposition of Carter's contentions above concerning the effect of the Wheeler Lea amendments, the major legal issue in this case; other than (a) to

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* Record references Petition, pp. 28-36.

** Record references Petition, pp. 19-20.

remark in passing without stating its reasons (Opinion, App. 51): "Parenthetically we point out that we disagree with Carter's contention concerning the effect of these amendments" and (b) to express in a footnote to its Opinion (App. 59) its complete miscomprehension of Carter's contentions in that regard. "As we view this argument", said the Court, "it at least carries the *suggestion* that the Commission's Order should not be sustained by this Court *if any conflict whatever* appears in the medical testimony of the expert witnesses concerning the truth or falsity of the various therapeutic claims appearing in Carter's advertising". Needless to say, no such contention nor suggestion was ever made then or now nor is any such suggestion entailed in any shape or form in Carter's argument.

(2) Apart from Congressional intent the requirements of the due process clause of the Fifth Amendment impel reasonable certainty "in fixing a standard for exacting obedience from a person in advance * * * as well in civil as in criminal legislation" *Cline* v. *Frink Dairy Co.*, 274 U. S. 445, 463. Accordingly, independently of legislative history or statutory construction or intent the basic constitutional need for a fair and certain standard of proof of falsity of a therapeutic claim compels the application in any event in the instant case of proof of falsity by the reasonable and certain standard of general informed medical agreement or consensus of medical opinion (Petitioner's Reply Brief, pp. 1-4).

3. The lower Court held (Opinion, App. 56) that "The Commission is deemed to have expert experience in dealing with matters of the character involved in the instant case" and that "our views (i.e., concerning the medical issues and the substantial difference and lack of agreement of general medical opinion) would have to yield to the special-

ized experience and knowledge of the Commission" (Opinion, App. 52). *But the Commission made no determination regarding the consensus of informed medical opinion nor as to the establishment thereby of the falsity of the claim.*

The lower Court's holding was both erroneous and a judicial abdication which resulted in depriving Carter of its statutory right to an independent and effective—as opposed to an illusory—judicial review of the basic issues in this case.

The holding is erroneous because (Carter's Reply Brief, pp. 6-14) (a) it is an inherent impossibility that this lay agency's determination of an unsolved medical controversy which neither it nor scientists themselves have ever before been called on to resolve with finality should be the product of this lay agency's accumulated experience or expert administrative judgment, (b) specific legislative history of the Wheeler-Lea Amendments demonstrates conclusively that there was no Congressional intention to repose special confidence in this lay Commission's judgment in controversial medical or scientific matters, (c) the holding introduces a dangerous innovation and a hitherto unknown restriction on the jurisdiction of courts which review the Commission's determinations in the field of medical and scientific matters not countenanced by any previous decision of this Court or of any other Federal Court, and (d) is diametrically in conflict both with the principles of the decisions of this Court and weighty textual authority regarding the doctrine of administrative expert judgment (Reply Brief, pp. 6-14).

Said the lower Court, "The judges of this Court are not equipped by education, training or experience to resolve a factual question of this character which obviously concerns the accuracy of the respective views of men practicing

medicine". (Opinion, App. 52). Of course, this lay Commission is not so equipped. But the chain of decision (*infra* B, pp. 15-21), as well as judicial determinations made under the Food and Drug, patent and other statutes, shows that neither federal courts of first instance nor federal appellate courts have ever before shrunk from judicial responsibility concerning scientific issues.

The holding is prejudicial in the extreme to Carter's rights. It vitiates completely the lower Court's review of this case. The holding demonstrates that despite its length and appearance of solidity and thoroughness the lower Court's Opinion is in reality nothing but the semblance of review.

Carter, therefore, stands before this Court, after more than 17 years of futile attempts to obtain review of its cause on the merits, with its principal contentions of law as yet unreviewed, and confronted, by this Court's denial of certiorari, with closure of the last avenue of judicial review of purely legal principles and issues which Carter submits are of prime, private and public consequence meriting settlement by decision of this Court.

The decision below on these issues was predicated on seven cases which the lower Court cited as authority for its Opinion (App. Opinion 53), none of which has any bearing on the issues in this case and whose citation by the Court betrays its misconception of the fundamental legal issues in this cause. "The following cases", said the Court, "hold that the Commission has authority to resolve conflicts in medical testimony":

> *Federal Trade Commission* v. *Raladam Co.*, 283 U. S. 643, 646; *Justin Haynes & Co.* v. *Federal Trade Commission*, 105 F. 2d 988, 989; *Dr. W. B. Caldwell, Inc.* v. *Federal Trade Commission*, 111 F. 2d 889, 891; *Neff* v. *Federal Trade Commission*, 117 F. 2d 495, 497; *D. D. D. Corp.* v. *Federal Trade Commission*,

125 F. 2d 679, 680, 682; *John J. Fulton Co.* v. *Federal Trade Commission*, 130 F. 2d 85, 86, citing cases, cert. denied 317 U. S. 679; *Aronberg* v. *Federal Trade Commission*, 132 F. 2d 165, 170.

Though the Court stated that it deferred to the Commission's expert judgement regarding consensus of informed medical opinion (App. Op. 52), *the Court overlooked the fact that the Commission failed to exercise its judgement at all on this issue because it made no determination or finding in that regard whatsoever.*

None of those decisions involved an unsolved medical controversy with regard to which there was a judicial finding that general informed medical opinion was itself in broad disagreement. In none of those cases—nor in any of the decisions cited by the Court in its Opinion (App, pp. 53-58) in support of its other holding—was it determined that the resolution, much less final resolution, of an unresolved schism in informed medical opinion had been confided to the expert judgment of this lay Commission.

I.

Substantial grounds not previously presented, and further reasons, why this case is the kind of case which poses questions of general importance which this Court should review.

A.

The decisions of the tribunals below have obliterated the distinction between fact and opinion. The issuance of the Commission's Order is an assumption of jurisdiction in a case not covered by the statute.

Absent fraud, an assertion of opinion is not a representation of fact and has, as a matter of fundamental law, no legal consequences because the assertion is incapable of proof or disproof as a fact.

Whether an assertion in the various fields of science is susceptible to proof or disproof as a fact or remains in the realm of pure opinion must, under the decisions of this Court, be determined by application of mathematical rules or scientific principles. *Gordon* v. *Butler*, 105 U. S. 553, 558; *U. S.* v. *Great Northern Ry. Co.*, 287 U. S. 144, 151-152. The susceptibility of the opinion to proof or disproof as a fact necessarily depends upon the nature and degree of exactitude of the principles of the particular science in which the assertion is made.

When as in the instant case, an inexact science or art is involved (*Stunz* v. *U. S.*, 27 F. (2) 575, 8th Cir.; *U. S.* v. *59 Tubes*, 32 F. Supp. 958, 962) where there are few absolutes and the particular medical topic in issue is further in a veritable state of controversy within the informed medical fraternity itself, the truth or untruth of any medical proposition concerned with that subject is necessarily undetermined. Until crystallization into general informed medical agreement occurs, assertions must by logical necessity remain pure opinion—though still scientific opinion—, susceptibility to proof or disproof as a matter of fact being lacking. In such case, until the disputed scientific issue is finally resolved by the medical community, truth or untruth can be nothing else but the majority of informed medical opinion, i.e., the consensus of such opinion. No other test of truth or falsity exists.

But as this Court held in *School of Magnetic Healing* v. *McAnnulty*, 187 U. S. 94, 106, with regard to therapeutic claims "Unless the question may be reduced to one of fact as distinguished from mere opinion, we think these statutes cannot be invoked * * *" * * * "The opinion entertained cannot, like allegations of fact, be proved to be false and therefore it cannot be proved as matter of fact that those

who maintain'' the opinion are within the scope of, or have violated, the statute (106).

It is all one w ther the opinion cannot be reduced to a question of fact because, as in the *McAnnulty* case, the opinion happens to lie entirely beyond the realm of science or whether the opinion's irreducibility to a question of fact is occasioned as in the instant case by an unsolved controversy or split in general informed medical opinion within the science or art itself.

Absent, as here, proof and finding that the falsity of the claim of effectiveness has been proved by general agreement of informed medical opinion or by test methods recognized by the consensus of such opinion, the Commission, in this case, ''has assumed and exercised jurisdiction in a case not covered by the statutes'' (*McAnnulty*, p. 107) just as surely as this Court held the Post Master General to have done, and enjoined him from doing, in that case.

The present cause furnishes in its most exaggerated form a case of first instance where the claim cannot be adjudicated false and hence is not covered by the Act because ''the charges concern medical practices in fields where knowledge has not yet crystallized in the crucible of experience'', *Reilly* v. *Pinkus*, 338 U. S. 269, 274, the ultimate effect of the statements of the Commission's own witnesses (Petition, pp. 25-26) being to establish that medical science has as yet failed to develop test methods adequate to determine the untruth of the claim.

B.

The chain of decision, with which the lower court's opinion is in conflict, establishes the proposition that disproof by consensus of informed medical opinion is an indispensable prerequisite to the conversion of an assertion of a medical opinion into a representation susceptible to disproof as a fact.

Here there is neither proof nor is there finding on the part of Court or Commission either of the existence of such a consensus of opinion or that disproof of Carter's claim was established thereby.

In departure from all precedent Carter has been singled out by the decisions below for special discriminatory treatment in this case.

The touchstone of "consensus of informed medical opinion" emerges from the uniform decisions of other Federal and Circuit Courts of Appeals in both civil and criminal proceedings as the crucial test of the susceptibility of a therapeutic opinion to proof or disproof as a fact. This test varies neither with the nature or specific provisions of the statute in question nor the character of the proceedings because what, as matter of basic law, is fact or opinion is necessarily so for all purposes.

(1) In *U. S.* v. *Dr. David Roberts Veterinary Co.*, 104 F. (2) 785 (7th Cir.) the Court found, 788, that the proof represented the "consensus of opinion" in the field in which the therapeutic claim was made, and accordingly held that "the question was reduced to one of fact as distinguished from mere opinion * * *". (788).

(2) In *Eleven Gross Packages* v. *U. S.*, 233 Fed. 71 (3rd Cir.) the Court found, 73, with regard to the therapeutic claim that "an examination of the proofs shows that the case was wholly different from one where witnesses were testifying to their views upon a controverted question of opinion. The testimony here was of fact, namely, that there was general, uncontroverted consensus of opinion" (73).

(3) In *McClean Medicine Co.* v. *U. S.*, 253 Fed. 694 (8th Cir.) the Court held concerning such a claim, "The testimony of the physicians as to their individual opinions of the efficacy of the preparation would have been properly rejected if there had been disclosed a difference of medical opinion on the subject" (696).

(4) In *U. S.* v. *Chichester*, 298 Fed. 829, 832 (C. A. D. C.) the Court held that proof of falsity of a therapeutic claim by consensus of medical opinion was impelled by this Court's decision in *Seven Cases* v. *U. S.*, 239 U. S. 510. This was one of the principal decisions of this Court cited in the Committee Report on the Wheeler-Lea Amendments (Petition, p. 12) in support of the legislative selection of proof of falsity by general medical agreement as the applicable standard of proof imposed by the present Act. In that case this Court held that the legislative history of the former Food and Drug Act demonstrated—just as Carter contends that the legislative history of the present Federal Trade Commission Act shows—that, 517, "Congress deliberately excluded the field where there are differences of opinion between schools *or* practitioners. Cong. Rec. 62nd Cong. 2nd Sess. Vol. 4, Part 12, App. p. 675."

(5) In *Simpson* v. *U. S.*, 241 Fed. 841, 845 (6th Cir.) the Court based its holding of falsity on its finding, 845, that "medical science and medical experience furnish no support" for the therapeutic claim and the "claims made for the medicine were contrary to all medical science", and in *Kar-Ry. Chemical Co.* v. *U. S.*, 264 Fed. 921 (7th Cir.) that the therapeutic claim "would not be recognized in any school of medicine". (925).

(6) In *U. S.* v. *Kaadt*, 171 F. (2) 600, (7th Cir.) the Court acknowledged the validity of the defendant's assertion "that before a court is warranted in submitting the

false or misleading qualities of an assertion of effectiveness to a jury to decide, it must be satisfied that something more is involved than mere difference of opinion between schools or practitioners", but responded by pointing out that the distinguishing factor in that case was that the expert medical testimony as to the worthlessness of the therapeutic claim (603) "represented the consensus of medical opinion of the authorities on diabetes".

(7) In *Fanning* v. *Williams*, 173 F. (2) 95 (9th Cir.), the lower Court here itself found with regard to the therapeutic claim there that (96) "There is no evidence in this record that trained and intelligent medical minds differ on the question that all persons cannot use the same diet with safety." In distinguishing the Circuit Court's decision in *Reilly* v. *Pinkus* (3rd Cir.) 170 F. (2) 786, the Court of Appeals for the Ninth Circuit held (p. 97) "In that case, however, there developed at the hearing a conflict of medical testimony to the therapeutic value of the product in question. • • • We have no such situation here. On the contrary, it affirmatively appears that the testimony given represented the consensus of scientific knowledge".

Again, in *U. S.* v. *El-O-Pathic Pharmacy*, 192 F. (2) 62, that same Court, in a civil suit for injunction under the present Food and Drug Act, whose provisions on misbranding and legislative history are identical with those of the Wheeler-Lea Amendments to the Federal Trade Commission Act, recognized that it had no right with regard to the therapeutic claim in question (74) "to act as an arbiter between conflicting medical opinions or schools of scientific thought"—just as Carter asserts the Commission has no right to do here. The Court enjoined the claim solely on the ground that (74) "while there is some difference of view" the difference—unlike the difference in the status of

informed medical opinion in Carter's case—was not substantial.

In a civil proceeding under the same Act, the Court in *U. S.* v. *23 Articles*, 192 F. (2) 308 (2nd Cir.), authorized suppression of the therapeutic claim on the sole basis of unanimity and agreement of medical opinion (309, 310), uncontradicted by defendant's experts (310). It referred also to admissions by defendant's experts that the claims were extravagant. No such issue as the latter is presented in the instant case. Carter asserts no right to make, and seeks no revision of the Commission's Order in so far as it prohibits, extravagant claims (Petition, p. 6). Carter asks reversal of the Order only as to its specific prohibition of Carter's single basic claim that the drugs in its product are an effective aid to bile flow and as to the Order's consequent prohibition of the use of the word "Liver" in the trade name of its product. (Petition, pp. 2-3).

(8) Such also is the effect of the Courts' holdings, under the former Federal Trade Commission Act, in *Silver Co.* v. *Federal Trade Commission*, 289 Fed. 990 (6th Cir.) and *Raladam Co.* v. *Federal Trade Commission*, 42 F. (2) 432, 435, aff'd. on other grounds, 283 U. S. 643; and of *Alberty* v. *Federal Trade Commission*, 118 F. (2) 669, 9th Cir., concurring opinion of Judge Healy, 671, cert. den. 314 U. S. 630 and *Alberty* v. *Federal Trade Commission*, 182 F. (2) 36, 40 (C. A. D. C.), cert. den. 340 U. S. 818 under the present Act.

(9) In none of all the many cases above cited did the appellate courts including the Ninth Circuit Court of Appeals itself, disclaim as it did in this case (App. Opinion, p. 32), ability to resolve medical issues or to apply the requisite constitutional and statutory standard of proof of falsity by general informed medical opinion. Nor did the Court

below experience any difficulty, in its former Opinion in this case (201 F. (2) 446), in deciding the relevance and materiality of the many complex medical issues involved in Carter's cross-examination of the Commission's experts whose unwarranted abridgement that Court held to be a denial of Carter's constitutional right to a fair trial.

(10) To the same effect as the decisions cited above is the thoughtful analysis by the Court in *U. S. v. 7 Jugs of Dr. Salsbury's Rakos*, 53 Fed. Supp. 746 of the identical legislative history* of the 1938 amendments to the Food and Drug Act concerning misbranding of drugs whose provisions** are identical with those of the false advertising section of the Federal Trade Commission Act contemporaneously incorporated in the *Wheeler-Lea* Amendments to that statute.

Reviewing the legislative history of these amendments to the present Food and Drug Act the Court concluded, 757 just as Carter contends with regard to the identical legislative history of the amendments here to the Federal Trade Commission Act—that Congress did not intend to permit a claim of effectiveness of a drug to be found false where medical opinion is divided but only "where the question of effectiveness is demonstrable as a fact".

"'Plainly, therefore', said the Court, 'the subject of regulation in the 1938 Act, as in its predecessors, is matter of fact, not matter of opinion. See House Committee Report No. 2139†, 75th Congress, 3rd Session. * * * The susceptibility of effectiveness to proof as a fact necessarily determines whether assertions can be adjudged false or misleading

* See Petition, pp. 12-16.

** Section 321, 21 U. S. C.

† Reproduced in part, Petition, pp. 12-16.

within the meaning of Section 502(a). Necessarily, therefore, whether in a given case the question of effectiveness is one of opinion or fact depends entirely upon the evidence which is introduced. Under the law as it now stands, before a court is warranted in submitting the false or misleading qualities of an assertion of effectiveness to a jury to decide, it must be satisfied that something more is involved than mere difference of opinion between schools or practitioners" (758).

Constitutional rights, the Court conceded (758), would be "invaded" where there has, as in the instant case, been an attempt "to find a claim of effectiveness false on the basis of evidence which indicated only a contrariety of opinion" (758). On the facts the Court held—contrary to the situation disclosed by the record in the present case (Petition, pp. 21-39)—that the test methods used to disprove the assertion of effectiveness of the drug were approved by general informed medical opinion. "These tests (759) were recognized by outstanding men of science as constituting *conclusive evidence by recognized scientific standards* that the remedies were wholly ineffective". Accordingly, the Court reached the conclusion, 759, that "Questions which previously were subjects *only of opinion* have *now* been answered with certainty by the application of *scientifically known facts*".

In the case at bar the record discloses that the subject represents not known facts but a scientific controversy (Petition, pp. 28-39) so great that the lower Court disclaimed all ability to resolve it (App. Opinion, p. 52). There is no proof nor finding that the test methods used to disprove the claim were recognized by consensus of informed medical agreement. Further, the record demonstrates that general informed medical opinion—including that of a Commission's expert (Petition, pp. 22, 25-26)—poses a

still more fundamental obstacle to disproof of the claim, namely, that adequate medical methods of measuring the functioning of the human liver are as yet lacking. The liver is, in other words, the dark continent of medicine, a still uncharted realm of medical surmise (Petition, pp. 28-29) (Compare, Opinion of Judge Woolsey, *U. S.* v. *59 Tubes*, 32 F. Supp. 958, 962).

Carter has therefore been convicted of a violation of the Federal Trade Commission Act on the basis of evidence which consequently presents nothing more than a contrariety of opinion in direct conflict with an unbroken chain of decision of other Federal and Circuit Courts and with the principles of decisions of this Court. Thereby also the lower Court has countenanced an Order of the Commission censoring and suppressing for all time the advocacy of an honest, harmless scientific opinion which is guaranteed to Carter by the First Amendment.

C.

The punishment by permanent injunction which has been meted out to Carter here is equivalent to conviction for the offense of medical heterodoxy.

Censorship and suppression by injunction in this case of Carter's therapeutic opinion is a denial of its right "of advocacy of opinion" (*Kingsley Pictures Co.* v. *Regents*, 360 U. S. 684, 689) under the First Amendment.

"The situation" (as the Court in *U. S.* v. *American Laboratories*, 222 Fed. 104, 106, a case arising under the former Food and Drug Act, observed in trenchant language applicable here)" in this view of it may be voiced in the phrase that the defendant, if punished, will have been punished for the crime of medical heterodoxy, and not for any offense against the law * * *. As the argument might concede, the weight of scientific medical opinion is against

him. Inasmuch, however, as the treatment is the subject of controversy, and its efficacy within the domain of opinion, the minority cannot be convicted of crime merely because they are outnumbered". Neither can a person be subjected to censorship and injunction for advocating a scientific opinion where, absent proof of the informed majority opinion, it is not shown that he is in the minority at all.

The historic instance of Pasteur and his notorious persecution by the French Academy of Medicine are stark reminders of the wisdom of this view. Good intentions and motives of the agency, the instrumentality through which this arbitrary and final determination of scientific truth by fiat has been accomplished here, even if they were present, are irrelevant. In an area where an administrative agency acts as prosecutor, court and jury all in one it is as this Court said in *Morgan* v. *U. S.*, 304 U. S. 1, 22 "endowed with vast powers." All the more important, therefore, that it act in strict accordance with constitutional and statutory standards of proof, for at best in general "To be engaged" —as so acute an observer of human and political behavior as Gladstone said—"in opposing wrong affords, under the conditions of our mental constitution, but a slender guarantee for being right".*

As a matter of logic and of overwhelming precedent, as heretofore set forth and analyzed, it follows under the facts and findings in this case that the necessary effect of the decisions of the tribunals below is to restrain Carter from asserting what is a pure opinion, through the permanent suppression by injunction of the freedom, "of advocacy of opinion" (*Kingsley* case, *supra*, 689) guaranteed to it by the First Amendment. That the voicing of an honest and harmless scientific opinion is

* "Time and Place of Homer", William Ewart Gladstone.

included "in the web of freedoms which make up free speech" (*Speiser* case, *supra*, 357 U. S. 513, 520) is not open to doubt. As Mr. Justice Douglas speaking for this Court in *Hannegan* v. *Esquire, Inc.*, 327 U. S. 146, 151, said with regard to the "power of censorship. Such a power is so abhorrent to our traditions that a purpose to grant it should not easily be inferred". There was no purpose to grant it here.

"Those who make their living through exercise of First Amendment rights are no less entitled to its protection than those whose advocacy is not hitched to a profit motive". *Cammerano* v. *U. S.*, 358 U. S. 498, concurring Opinion of Mr. Justice Douglas, p. 514. As he justly there remarked, "The extent to which such (i.e., commercial) advertising can be regulated consistently with the First Amendment has * * * never been authoritatively determined" p. 513. It should be authoritatively determined by this Court here.

That it may take an effort of imagination to discern the larger implications of suppression of the therapeutic opinion of the manufacturer of a particular proprietary medicine is all the more reason why that effort should be made. Extinction of freedoms by absolute power is an imperceptible and stealthy process seldom clearly heralded. Courts in an age of science and technology must therefore be the more sensitive to recognition that preservation of freedom to express scientific opinions is of equal dignity and urgency with that of political, religious or esthetic expression or belief.

Carter is the first victim of this departure from all precedent and constitutional sanctions; it will not be the last. What was done here, under the false precedent of the decisions below repudiating as they do Fifth Amendment standards of proof and First Amendment safeguards, can

now be done with equal ease in the future to the therapeutic claims, no matter how substantial, of every drug or method of treatment, both new and old, in the whole arsenal of medicine.

The decision of the lower Court arms the Commission with a lethal weapon. All that the Commission now need do to expurgate a therapeutic opinion is to seek out a handful of experts who will be willing to testify to their individual opinion of the falsity of the claim or to devise some bizarre* test methods—unrecognized by general medical agreement—which in their individual opinion suffice to demonstrate its falsity. The Commission may rest safe in the assurance which the lower Court's Opinion gives it that courts' self-declared lack of equipment to deal with technical medical matters and their unmitigated deference to the supposititious expert judgment of the Commission in unsettled scientific controversies will protect the Commission's determination, however arbitrary, against all real judicial scrutiny or review.

Carter affirms in all good faith and confidence that if this Court will but re-examine and reconsider the analysis of the state of the record and the lower Court's findings in this case made in the Petition for Certiorari, in the light of the chain of judicial precedent and legislative background of the present Act, this Court will be led to these conclusions: If the limits of both medical uncertainty and undemonstrability were not both reached and passed as regards the controversial medical subject matter of this case, then those limits never can be. If this case does not present the prime instance for the application of these statutory and constitutional standards of proof and safeguards to the Commis-

* The lower Court's original Opinion so described the experiments of one of the Commission's principal experts, Dr. Bollman, 201 F. (2), p. 451 (App. 82).

sion's determination here, then those standards and those guarantees can never find use or application in any proceeding brought to suppress a therapeutic claim under that Act,

II.

Conclusion.

This Court should grant the writ requested on the grounds urged here and in Carter's Petition for Certiorari No. 366, for the purpose of settling important private and public issues posed by this case.

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Respectfully submitted,

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I hereby certify that the foregoing Petition for Rehearing is presented in good faith and not for delay and is restricted to grounds specified in Rule 58 of the Rules of this Court.

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